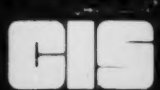
NOTE

This Microfiche meets the quality requirements of the American National Standard for Microfiche of Documents (ANSI PH5.9-1975). However, because of imperfections in the document from which it was made, it contains images that are illegible or difficult to read. The source document for this microfiche is the best copy that could be obtained prior to filming.



Congressional Information Service,
Washington, D.C.

101st Congress
1st Session

COMMITTEE PRINT

S. PRT.
101-55

GOVERNMENT REGULATION OF PESTICIDES IN FOOD: THE NEED FOR ADMINISTRATIVE AND REGULATORY REFORM

REPORT

BY THE

SUBCOMMITTEE ON TOXIC SUBSTANCES, ENVIRONMENTAL OVERSIGHT, RESEARCH AND DEVELOPMENT

TO THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

OCTOBER, 1989

Printed for the use of the Senate Committee
on Environment and Public Works

U.S. GOVERNMENT PRINTING OFFICE

22-520 WASHINGTON : 1989

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

S322-3

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

QUENTIN N. BURDICK, North Dakota, *Chairman*

DANIEL PATRICK MOYNIHAN, New York	JOHN H. CHAFEE, Rhode Island
GEORGE J. MITCHELL, Maine	ALAN K. SIMPSON, Wyoming
MAX BAUCUS, Montana	STEVE SYMMS, Idaho
FRANK R. LAUTENBERG, New Jersey	DAVE DURENBERGER, Minnesota
JOHN B. BREAUX, Louisiana	JOHN W. WARNER, Virginia
HARRY REID, Nevada	JAMES M. JEFFORDS, Vermont
BOB GRAHAM, Florida	GORDON J. HUMPHREY, New Hampshire
JOSEPH I. LIEBERMAN, Connecticut	

DAVID M. STRAUSS, *Staff Director*
ROBERT F. HURLEY, *Minority Staff Director*

LETTER OF TRANSMITTAL

QUENTIN N. BURDICK, NORTH DAKOTA, CHAIRMAN
DANIEL PATRICK MOYNIHAN, NEW YORK
GEORGE J. MITCHELL, MAINE
MAX BAUCUS, MONTANA
FRANK R. LAUTENBERG, NEW JERSEY
JOHN B. BREAUX, LOUISIANA
HARRY REID, NEVADA
BOB GRAHAM, FLORIDA
JOSEPH I. LIEBERMAN, CONNECTICUT
JOHN H. CHAFEE, RHODE ISLAND
ALAN K. SIMPSON, WYOMING
STEVE SYMMS, IDAHO
DAVE DURENBERGER, MINNESOTA
JOHN W. WARNER, VIRGINIA
JAMES M. JEFFORDS, VERMONT
GORDON J. HUMPHREY, NEW HAMPSHIRE
DAVID M. STRAUSS, STAFF DIRECTOR
ROBERT F. HURLEY, MINORITY STAFF DIRECTOR

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

September 22, 1989

The Honorable Quentin N. Burdick
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable John H. Chafee
Ranking Minority Member
Committee on Environment and Public Works
United States Senate

Dear Chairman Burdick and Senator Chafee:

The Subcommittee on Toxic Substances, Environmental Oversight, Research and Development has completed a report entitled, "Government Regulation of Pesticides in Food: The Need for Administrative and Regulatory Reform". The report contains the Subcommittee's findings and recommendations based on several months of inquiry into the pesticide regulatory process and a hearing on pesticide issues.

The Subcommittee's interest in pesticide use, health and environmental risks and regulation was initially prompted by the controversy concerning Alar, a growth regulator applied to apples and other crops. A hearing was conducted on May 15, 1989 to review regulation of Alar, the pesticide regulatory process generally, and potential acute and chronic neurotoxic effects of exposure to pesticides. Subsequently, a voluntary withdrawal of Alar from the domestic market was negotiated between the manufacturer and EPA. Further, under a schedule proposed by the Agency, the tolerance level for Alar in food will be reduced to zero by June, 1991.

As described in the Subcommittee's report, many shortcomings are inherent in the pesticide regulatory process and reforms are needed. A serious disservice is done to the public and particularly the nations farmers if confidence in the process breaks down, as illustrated by the Alar incident. The Subcommittee's findings and recommendations nopefully will serve as a useful platform for stimulating constructive changes in that process.

All members of the Subcommittee have been given the opportunity to review and comment on this report. With the unanimous approval of the Subcommittee members, I hereby transmit the report and additional views to the Committee for publication.

Sincerely,

Harry M. Reid
Chairman
Subcommittee on Toxic Substances
Environmental Oversight, Research
and Development

CONTENTS

Page

I. Introduction..... 1
II. Background..... 3
A. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)... 4
B. Federal Food, Drug, and Cosmetic Act..... 9
C. The FIFRA registration procedure--5 to 7 years.....11
D. Tolerance setting and the Delany Paradox.....18
III. The Alar story.....25
A. The history of research on Alar.....25
B. Subcommittee review of EPA regulation of Alar.....32
C. Subcommittee Members introduce legislation to ban Alar.....40
D. Conclusion.....42
IV. Other failures in EPA pesticide regulation.....44
A. EPA's failure to protect us from the most dangerous chemicals.44
B. Setting tolerances for processed foods.....45
C. When should EPA invoke the iminent hazard provision.....46
D. Review of synergistic and cumulative effects.....48
E. Protecting sensitive subpopulations.....50
F. Review of neurotoxic effects.....54
G. Captan.....57
V. Conclusions/recommendations.....59
A. Review of top ten most dangerous pesticides.....60
B. The Scientific Advisory Panel.....61
C. Suspension and iminent hazard.....62
D. Overall plan and schedule.....63
E. Resolve conflicts between risk-benefit analysis and Delany Clause.....65
F. Neurotoxicity testing.....66
G. Shorter review time for certain chemicals.....67
H. Tolerance levels should equal safe exposure levels.....69
I. Setting tolerances based on health effects and effects and effects on subpopulations.....70
J. Cumulative and Synergistic effects.....71
K. Inert ingredients.....72
L. Detection of residues in food.....72
Footnotes.....73
Additional views of Senators Warner and Jeffords.....77
Appendices:
1.....85
2.....89
3.....97

GOVERNMENT REGULATION OF PESTICIDES IN FOOD: THE NEED FOR ADMINISTRATIVE AND REGULATORY REFORM

I. INTRODUCTION

On May 15, 1989 the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development of the Committee on Environment and Public Works held an oversight hearing to review the process by which the Environmental Protection Agency (EPA) regulates pesticide products used on food. This report describes the EPA's regulation of pesticide products and recent problems with that regulatory process. The report also presents recommendations for regulatory reform. In order to understand the current problems associated with the regulation of pesticides in food, it is necessary to review in some detail the history of pesticide statutes and the conflicts between the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA).

The first section of this report includes a background discussion on government regulation of pesticides in food, including the history of FIFRA and FFDCA. It traces the evolution of FIFRA from a business regulation statute designed to protect farmers who purchase pesticides to an environmental

protection statute attempting to regulate the effects of pesticides on those who consume treated foods. This section also reviews several paradoxes created by existing pesticide regulation, including the different treatment of chemicals which came on the market prior and subsequent to 1972, and the different pesticide residue tolerance requirements for raw produce and for processed foods.

The report then reviews the history of the regulation of Alar. The Alar story is an excellent example of the myriad problems which exist today in the area of pesticide regulation. It illustrates the length of time it takes EPA to remove a potentially harmful chemical from the market. It also provides the background for the Subcommittee's concerns about the impartiality of the Scientific Advisory Panel which reviews pesticide decisions for EPA. Finally, it details the particular problems which may arise when a pesticide is used on a food consumed in large amounts by children.

The report then reviews concerns about EPA's pesticide regulation process that were expressed by witnesses at the Subcommittee's hearing, and were highlighted by the Alar story. These concerns include: whether or not EPA places sufficient emphasis on the health of sensitive subpopulations in its regulation of pesticides; the need for regulating the neurotoxic

effects of pesticides; delays in the reregistration process; and EPA's seeming reluctance to invoke the "imminent hazard" provision and the fact that it does not interpret the provision as it does in the implementation of other environmental statutes.

The final section of the report includes the Subcommittee's conclusions and recommendations for reform of EPA's pesticides program. These recommendations are presented with the goal of guiding the implementation of the amendments to FIFRA which Congress enacted in 1988, bringing the management of the pesticide regulation program up to date as rapidly as possible, and ensuring that the health of the American consumer, the cleanliness of the environment, and the welfare of the American farmer are protected.

II. BACKGROUND

An examination of pesticide regulation and use in America today raises concerns about the amount of chemicals being used by farmers and the way in which those chemicals are regulated by the Environmental Protection Agency. The May 15, 1989 hearing held by the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development of the Senate Committee on Environment and Public Works focused on the failure of EPA to adequately

regulate those chemicals used on food. In order to properly analyze the reasons for this failure, it is necessary to examine the history of pesticide regulation in this country.

A. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. Sections 136 to 136y, controls the registration of pesticides for use on food. Rooted in a 1910 statute designed to protect farmers who use pesticides from false marketing claims, FIFRA has evolved towards concentrating on the health and environmental safety aspects of pesticide use. FIFRA now requires balancing the benefits of a pesticide's use against its potential risks to human health and the environment. FIFRA was under the jurisdiction of the Department of Agriculture (USDA) until the creation of the Environmental Protection Agency in 1970.

1. 1947 -- FIFRA Is Enacted To Protect Farmers

Pesticide regulation began in 1910 with truth in packaging legislation to protect the farmer who relied on pesticides such as sulfur, mercury and copper compounds. Synthetic organic pesticides were developed during World War II for use in the war. After the war, the pesticide industry grew rapidly. In 1947,

Congress enacted FIFRA which was designed to protect farmers from ineffective or dangerous pesticides by requiring that labels be placed on all pesticide products. The authority to regulate pesticide use is based on the requirement that before a pesticide can be sold, it must be granted a "registration."[1]

Registration decisions determine what crops the pesticide may safely be used on, and what restrictions on use are necessary. A particular use of a pesticide is permitted if EPA determines that a certain amount applied to a particular crop according to specific application instructions will not adversely affect public health and safety or the environment. Restrictions may include the amount permissible as well as the number of times during the growing season the pesticide may be applied, the last permissible application date prior to harvest, and instructions for users on how the pesticide is to be applied. Both the restrictions and the crops to which the pesticide may be applied are listed on the required label.

2. 1972 -- FIFRA Amendments to Monitor Residues and Environmental Effects

In the decades following 1947, concern about hazards to health and the environment from pesticides increased. In 1972 Congress enacted the Federal Environmental Pesticide Control Act of 1972 (Pub. Law No. 92-516). This Act, which contained amendments revising FIFRA, provided for additional direct government control of the use of pesticides, for classification of selected pesticides into a restricted category, for registration of manufacturing plants, and for a national monitoring program for pesticide residues. It also added environmental effects to the risks to be weighed in the pesticide registration process, and required a review of older pesticides, called "reregistration" to ensure that they meet modern data requirements.

EPA's difficulties with its pesticides registration program began when it took over the enforcement of FIFRA from USDA in 1970. The Agency has been the target of criticism both from environmental and consumer groups who believe much stricter regulation of pesticides is necessary and from some business and agricultural interests who believe FIFRA is often unnecessarily stringent.[2] Many farmers complain that often, as in the Alar episode, they get caught in the middle of this conflict.[3]

3. 1978 -- Reregistration for Generic Chemicals

The Federal Pesticide Act of 1978 (Pub. Law No. 95-396) was an attempt to respond to problems arising from attempts to implement the 1972 amendments to FIFRA. The Act attempted to expedite the reregistration process by allowing for registration on the basis of the generic chemical active ingredient. The active ingredient is the particular chemical in the pesticide product that kills or controls the insect, weed, or fungus. The pesticide product may also contain other chemicals, inert ingredients, used to facilitate application of the active ingredient. The 1978 amendments also instituted conditional registration, limited data requirements for minor uses of pesticides, and gave pesticide developers a 10-year exclusive use of data. In addition, states were delegated additional enforcement responsibilities. Pursuant to the transfer of FFDCA jurisdiction to EPA in 1970, the Agency sets residue tolerances, and the FDA monitors food products to determine that residues are within required limits. The states, however, have the authority to set tolerances below the levels found acceptable by the federal government. The 1978 amendments also require the Agency to consult the Scientific Advisory Panel (SAP) in order to monitor the quality of EPA's risk assessment analysis. Finally,

the amendments required EPA and USDA to explore integrated pest management (IPM).[4]

4. 1988 -- A Timetable for Reregistration

By the mid-1980s it became clear that despite the 1978 amendments reregistration was not being accomplished at an acceptable pace. Additional amendments enacted in 1988 establish a timetable for reregistration, designed to ensure that the process did not extend into the 21st century, and attempt to ensure that EPA has adequate funds to complete reregistration. The amendments require EPA to complete reregistration in 91/2 years and establish annual registration fees to help support EPA's pesticide registration program. They also set forth a reregistration schedule, shifting some of the administrative burdens for making initial determinations about which data is missing from files and which is inadequate to the registrants. Registrants must now review their files and identify for EPA the data needed for each registration, the data submitted which was "inadequate," and the data which was not submitted.

5. Pesticide Use in the United States Today

From 1964 to 1982 the amount of pesticide active ingredients used by farmers increased by 170 percent.[5] As farmers have increased their reliance on the use of chemicals, pests have become more resistant to chemicals.[6] The increasing resistance of pests has led to the use of more and more chemicals. As farmers have increased their reliance on chemicals -- at ever-growing cost[7] -- the government has been slow to strengthen its ability to help farmers know which chemicals are safe and how much of each chemical should be used nor has the government devoted sufficient resources to teaching farmers how to use fewer chemicals while retaining their yield.

B. Federal Food, Drug and Cosmetic Act (FFDCA)

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, et seq., is the primary food safety statute. The Act is administered by the Food and Drug Administration, although the EPA is responsible for setting the permissible pesticide residue levels. Under FFDCA, the EPA must establish legal limits or "tolerances" specifying the amount of pesticide residue that can be present in or on foods sold in interstate commerce. Sections 408 and 409 of the FFDCA focus on the regulation of pesticide residues in food. Section 408 authorizes the setting of tolerances for raw agricultural commodities. EPA has interpreted

Section 408 as requiring not only recognition of the risks and benefits from pesticide use, but also a balancing of these risks and benefits when setting tolerances. The statute, however, does not state that a risk-benefit analysis must be done; it states that the Administrator must give "appropriate consideration" to a number of factors including "the necessity for the production of an adequate, wholesome, and economical food supply." (21 U.S.C. Section 346a(b))

Section 409 governs food additives and, therefore, covers certain pesticide residues on processed foods. The Delaney Clause, part of Section 409, states that "no additive shall be deemed safe if it is found to induce cancer when ingested by man or animal...." (21 U.S.C. Section 348(c)(3)(A)) Pursuant to the Delaney Clause, EPA is barred from granting a tolerance in processed foods for any pesticide which causes cancer in humans or animals regardless of the estimated risk. EPA has proposed an interpretation of the Delaney Clause which would allow it to grant a tolerance for a pesticide with a negligible risk; although, EPA has not established a numerical boundary for negligible risk.

The Delaney Clause was included in the 1958 Food Additive Amendment which resulted from a congressional investigation of the use of chemicals in food production. The House Select

Committee to Investigate the Use of Chemicals in Food and Cosmetics, chaired by Congressman Delaney, issued a report in 1952 on the use of chemicals in food production. (H.Rept. No. 2356, 82d Cong., 2d sess.1 (1952)). The report discussed the large number of chemical compounds which cause cancer in animals. The Select Committee recommended that the House enact legislation to control hazardous chemical substances in the nation's food supply. (H.Rept. No. 2356, 82d Cong., 2d sess.1 (1952))

In response to this report a number of bills were introduced in the 83rd Congress to address concern over pesticides.[8] During the same Congress legislation was introduced to deal with food additives. Rep. Delaney introduced a bill which included a provision regulating carcinogens, now known as the Delaney Clause. The FDA objected to the Delaney Provision and the Food Additive Amendment was reported without the Delaney Clause; however, Rep. Delaney convinced the Committee to include the clause prior to the bill be taken up on the floor of the House.

C. The FIFRA Registration Procedure - 5 to 7 Years

Under FIFRA, 7 U.S.C. Sections 136, et seq., as amended, there are two different procedures for the registration of pesticides. One procedure governs new chemicals not yet on the market as of 1984. The other, reregistration, applies to those chemicals which were allowed on the market prior to 1984.

1. Registration of New Products

When a company wishes to introduce a new chemical to the market, the applicant for registration, known as the "applicant," is responsible for developing and submitting health and environmental data to establish the product's safety. Collection of the necessary data for registration takes 4 to 6 years and the entire registration process may take over 7 years. The cost to the applicant of developing and registering a new pesticide is estimated to be upwards of $10 million.

The data necessary for registration includes information on health and environmental effects, including carcinogenicity, product chemistry, aquatic toxicity, and mutagenicity. This information is used to establish any restrictions on use, including the produce on which the pesticide may be used and the permissible application rates.[9] The EPA also determines how much of the pesticide's residue is allowed to remain on the

treated commodity: the residue "tolerance". Data requirements have been modified over the years in response to changes in our ability to evaluate pesticides and their potential health and environmental effects. If the data requirements change after the product has been registered, the product is permitted to remain in use while EPA determines what new data should be generated, evaluates any newly submitted information, and possibly revises the tolerance and limits on use.[10]

2. Reregistration

The 1972 FIFRA Amendments (Pub. Law No. 92-516) required a review of all then-registered pesticide products in order to reevaluate their safety and determine whether their registrations should be renewed. This process is called "reregistration."[11] The 1972 FIFRA amendments required EPA to complete the review of all registered pesticide products within three years; however, GAO has testified that as of April 28, 1989 reregistration had not been completed for a single chemical. (Hearing, Prepared Testimony, p. 139)*

* Unless otherwise noted, all references to "Hearing" cited throughout this report will be the following: "Chemicals and Food Crops" hearing held before the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development of the Committee on Environment and Public Works, United States Senate, May 15, 1989, hearing number 101-107.

In 1976, it became evident that reregistration could not possibly be completed even in 10 years. EPA discovered that much of the health and safety data submitted over a 30-year period would need to be completely reevaluated. Inadequate data, pursuant to current scientific standards, existed for most of the major previously registered pesticides. The data most lacking concerned potential chronic health effects. For example, although current carcinogenicity testing standards date from the mid-1970's, the tests on most already-registered pesticides were done much earlier, using less sophisticated standards. Before even beginning reregistration, EPA had to review all product files just to determine if all the necessary data was in and if it complied with contemporary scientific standards.[12]

To help EPA complete the herculean task of reregistration, the 1978 amendments to FIFRA (Pub. Law No. 95-396) authorized it to group the estimated 50,000 registrations by active ingredient and conduct a "generic" review of the active ingredient's safety. These generic Registration Standards review regulatory information about pesticide products on an active ingredient basis. The Registration Standard identifies data gaps, but almost never provides a final reassessment of the safety of the products containing the active ingredient. Often the Registration Standard reveals what is not known about a

pesticide, rather than what is known. Only when all the missing data and any newly required data are submitted, can a complete safety review of all currently registered products be conducted.

Pursuant to the 1978 amendments EPA has identified 600 groups of chemically similar compounds out of the 1500 active ingredients which have been registered. There are over 40,000 studies on these active ingredients in EPA's files. Through 1988, EPA had completed 194 of the 600 Registration Standards. When a Registration Standard is completed, EPA then must wait for the necessary data to be developed. The data collection process may take 4 years or more. When the data are in, the Agency must review it to determine which chemicals should be reregistered.[13] GAO testified that since reregistration began in 1972, no product reregistrations have been completed. (Hearing, Prepared Testimony, p. 139) EPA agreed at the May 15 hearing that it has "not formally 'reregistered' any active ingredient." (Hearing, Prepared Testimony, p. 181)

In its testimony presented on May 15, 1989 GAO reviewed the status of reregistration as of April 28, 1989. GAO now estimates that there are 35,000 pesticide products which must undergo reregistration. The 35,000 pesticide products contain, according to GAO: 1,300 individual active ingredients which EPA has

divided into 822 commercially important active ingredient cases containing active ingredients with similar chemical characteristics. GAO estimates 822 rather than EPA's original estimate of 600, because they include those pesticides which were registered between 1972 and 1984. (Hearing, Prepared Testimony of Peter Guerrero, p. 139) During the initial steps of the reregistration process, some ingredients have been voluntarily withdrawn or canceled; therefore, the final number which needs to be reregistered will be less than 822. (Hearing, Prepared Testimony of Peter Guerrero, p. 139; Prepared Testimony of Dr. John Moore, p.181)

As of April 28, 1989 approximately 70 active ingredients have been either cancelled voluntarily by registrants or suspended by EPA. 194 List A interim registration standards, representing most of the major food-use pesticides, have been developed. These are "interim" standards because EPA lacks sufficient data to fully assess the pesticides. Of the 194 interim registration standards, 24 were subsequently cancelled or suspended, 18 second round reviews were developed with the reregistration assessment incomplete, and 152 await second round review. GAO's review concluded that no reregistration assessments had been completed (Hearing, Prepared Testimony of Peter Guerrero, p. 139).

In order to reregister a pesticide EPA must also reassess the tolerance level for both raw and processed food. According to GAO, EPA estimates that 387 active ingredients used on food need tolerance reassessments. Of these 387, interim standards have been developed for 167, 14 were subsequently cancelled or suspended and second round reviews have been developed for 18. EPA maintains that tolerance reassessment has been completed on 4 pesticides, and all tolerance actions have been completed for 3 out of the 387 food-use active ingredients. (Hearing, Prepared Testimony of Peter Guerrero, pp. 134, 140)

In 1986, GAO estimated that under EPA's existing procedures it would not complete reregistration until the year 2024. In an attempt to insure completion of this task prior to the year 2000, Congress amended FIFRA in 1988 to require the completion of reregistration over the next 91/2 years. Even under the most optimistic scenario it would not be possible to complete reregistration prior to 1995, since long-term laboratory animal studies require up to four years to complete, EPA then requires a minimum of one year to review the data, and additional time is needed to implement any appropriate regulatory changes.[14]

D. Tolerance Setting and The Delaney Paradox[15]

1. The Standards Governing Tolerance Setting

In order to register a pesticide, the tolerance or level of residue permissible on or in the product must be set and in order to cancel a pesticide and guarantee that no one is exposed to the residue, the tolerance must be revoked. The existence of conflicting legislative standards in setting tolerances for raw agricultural commodities compared to processed food products is the source of some of EPA's most significant problems with the regulation of chemicals used on food.

As outlined earlier in this report, two different sections of the FFDCA govern the setting of tolerances. Section 408 authorizes establishment of tolerances for pesticides in or on raw agricultural commodities before they leave the farm gate. These tolerances are supposed to be set at the level adequate to protect the public health, while taking into account the need for an adequate food supply. Like the standards for registration under FIFRA, Section 408 has been interpreted by EPA to require consideration of both risks and benefits in establishing tolerances.

The standards for granting a tolerance under Section 409 differ from the risk-benefit consideration required in Section 408. Section 409 requires the sponsor of a food additive to prove with reasonable certainty that no harm to consumers will result when the additive is put to its intended use. Pursuant to the Delaney Clause, also in Section 409, food additives that have been found to cause cancer in humans or animals cannot be granted a tolerance. Unlike Section 408, the language of Section 409 does not appear to allow any consideration of economic or other benefits derived from the additive. Tolerances for pesticide residues which concentrate in processed food are set under the same risk-only standard that governs intentional food additives: the residue must be proven safe and cannot cause cancer in animals or humans. The so-called "Delaney Paradox" arises from the difficulty of reconciling the zero cancer risk standard in Section 409 with the risk-benefit analysis allowed by FIFRA and applied to Section 408.

2. Setting Tolerances for Suspected Oncogens

In 1958 when Congress enacted Section 409, it exempted from the definition of food additive those pesticide residues which appear in processed food at levels no higher than the tolerance level for raw agricultural commodities. Under this exemption some pesticides residues are not subject to the Delaney Clause.

In some cases where the raw produce tolerance levels have been set intentionally high to account for widely varying conditions of potential use and old food use tolerances have not been reassessed, EPA has not needed to set Section 409 tolerances.

Under Section 408, if EPA determines that a pesticide, or its expected impurities or metabolites[16] do not cause a statistically significant increase in the incidence of tumors in animals, then it concludes the Delaney Clause is not applicable. The Agency then establishes the tolerance by first calculating the Acceptable Daily Intake (ADI), the highest level of pesticide exposure at which no adverse effect is observed, "No Observed Effect Level" (NOEL), and applying certain safety margins. EPA then calculates the theoretical maximum residue contribution of the treated food. The tolerance is then set at a level such that an individual will not consume more than the Acceptable Daily Intake .[17]

If the pesticide is a suspected oncogen, the EPA's Section 408 analysis proceeds somewhat differently. The Agency does not seek to identify a NOEL; instead, it develops quantitative risk assessment models specifically to provide upper-bound estimates of human cancer risks assuming a lifetime of exposure to the pesticide. On the basis of these risk assessments, the EPA makes

a judgement about whether a given tolerance for a specific pesticide use poses an unreasonable risk to humans, or whether the risk is negligible enough to justify a tolerance. The EPA has not formally adopted any numerical cutoff delineating those oncogenic risks it views as negligible. Review of EPA tolerance actions in recent years suggests that, in most cases, the Agency's finds risks negligible when the estimated upper-bound risk is less than one additional cancer case per million people exposed.

In setting tolerances for oncogenic pesticides EPA must apply the Delaney Clause. If a pesticide's residues concentrate in some processed foods and it has been found to be oncogenic in animals, then, pursuant to Section 409, there can be no consideration of whether the residue poses a risk to humans or whether the risk might be judged acceptable. EPA cannot grant a tolerance for use on processed food. Since 1978 EPA has not granted a processed food tolerance for a pesticide with an oncogenic active ingredient.[18] However, the Agency has not invoked the Delaney Clause in order to repeal an existing tolerance.[19]

3. The Paradoxes Of The Tolerance Setting System

The current system treats pesticide residues inconsistently in two ways. The first is exemplified by the different standards for setting tolerances set forth in Sections 408 and 409. There is no sound scientific or policy reason for the legislative determination to regulate pesticides present in or on raw commodities differently than those present on processed foods. From the standpoint of consumer protection, the source of exposure -- raw commodity versus processed food --is irrelevant.

The second inconsistency is the system's disparate treatment of so-called "old" and "new" pesticides.[20] Old pesticides, especially those first registered before 1972 generally were not tested adequately according to current standards for oncogenicity or chronic long-term effects. (Hearing, Testimony of Peter Guerrero, GAO, p. 28) They were approved on the basis of limited residue chemistry data, particularly concerning metabolites. Consequently, there was very limited knowledge of the pesticides' capacity to concentrate in processed food. Many of these pesticides are widely used today, even though some are suspected oncogens and usually lack Section 409 tolerances that would be required if complete residue chemistry data were available. Pesticides recently registered for use on foods, on the other

hand, have generally been tested rigorously. As more complete residue chemistry data is collected, the EPA is likely to recognize the need for Section 409 tolerances which, if a pesticides presents any oncogenic risk, cannot be granted.

The paradox which results from strict adherence to the Delaney Clause in establishing new tolerances is that the Delaney Clause may preclude commercial introduction of new, potentially lower-risk, pesticides. If these lower-risk pesticides cause even a very low level of cancer in animals they are barred by the Delaney Clause from being placed on the market to replace older, potentially more hazardous compounds that have not been fully tested or, if tested, have not been brought into compliance with all current statutory requirements. As Dr. Charles M. Benbrook, Executive Director of the Board on Agriculture, National Research Council, noted at the hearing, "The Delaney Clause standard and the strict requirements of a complete data set stop safer alternatives from coming on the market. Yet, EPA, because it has to live within the risk-benefit standard of the FIFRA act, cannot cancel the old products because there are no benefits [alternatives]. If that isn't a Rube Goldberg situation, I've never heard of it." (Hearing, Testimony of Dr. Charles Benbrook, p. 26)

EPA also faces difficulties in reducing tolerances for major food uses of pesticides which are now suspected oncogens. As Dr. Benbrook testified, "lowering the Section 408 raw agricultural product tolerances will routinely -- but not always -- create the need to establish some higher Section 409 tolerance to cover the concentrating residues in some processed foods. Alas, the Agency would be blocked by the Delaney Clause from doing so when a pesticide has been found to cause cancer in man or animals." (Hearing, Prepared Testimony of Dr. Charles Benbrook, pp. 111-12) It appears that in order to avoid this potential conflict, EPA has not attempted to lower the Section 408 tolerance as one possible way to reduce the risk to public health. EPA, instead, chooses to leave the tolerance level where it is and/or cancel all or some of the uses of a chemical, rather than lower the tolerance across the board. (Hearing, Prepared Testimony of Dr. Charles Benbrook, pp. 112)

According to Dr. Benbrook, "EPA has deferred applying the Delaney Clause to old pesticides because of the burdensome standard under FIFRA and [the] process which must be followed to cancel a pesticide use." EPA has used the Delaney Clause to deny tolerances and registrations to new, very weakly oncogenic pesticides with low risk levels, while, at the same time, the Agency has not applied the Delaney Clause to older oncogenic

chemicals with much higher risk levels. (Hearing, Prepared Testimony of Dr. Charles Benbrook, p. 114)

III. THE ALAR STORY

A. The History of Research on Alar

Part of the impetus for the hearing and much of the testimony presented at the hearing concerned the chemical Alar. Alar provides a good case study for many of the regulatory problems discussed above in the report.

1. 1973 -- The First Evidence of Carcinogenicity

Daminozide, trade name Alar, was registered in 1963 for ornamental uses such as flowers, and in 1968 for its first food use. Until June 1989 it was used primarily on apples to prevent preharvest fruit drop, increase storage life, and to promote red color. Daminozide is also used on peanuts and cherries. The EPA first received evidence in 1973 which suggested that an inevitable metabolite of daminozide, unsymetrical dimethlyhydrazine (UDMH), caused cancer. Evidence that daminozide caused cancer in animals was discovered in 1977. As

with the 1973 studies, UDMH, which concentrates in greater amounts when the treated crop is heat processed, was of particular concern. As a result of processing, apple products such as applesauce and apple juice may contain elevated levels of UDMH. UDMH, which is also a component of rocket fuel, was of interest to the United States Air Force which conducted laboratory tests to determine possible risks from occupational exposures for aerospace workers.

2. The 1980 Special Review

In 1980 EPA took steps to begin a "Special Review" of daminozide. A Special Review is an intensified review of the pesticide's risks and benefits in light of new data suggesting levels of risk not considered at the time of the pesticide's original registration. However, after EPA and the manufacturer of Alar, Uniroyal Chemical Company, had private meetings which were closed to the public and to other interested parties, EPA decided not to initiate a Special Review of the pesticide's risks and benefits.[21] Since these meetings were secret, it is not clear whether there were substantive grounds for the decision not to continue with the Special Review or whether the review was discontinued as a result of some kind of influence brought to bear by the manufacturer.

As the result of a settlement reached in litigation initiated by the Natural Resources Defense Council (NRDC) concerning the practice of private meetings between EPA and pesticide manufacturers on the regulation of their products, EPA was required to hold open meetings to discuss their regulation of pesticides. (Natural Resources Defense Council, Inc. v. Environmental Protection Agency, No. 83-1509 (D.D.C., Oct. 10, 1984)) In July 1984, EPA once again began a Special Review of daminozide. That Special Review was put on hold in September 1985.

In September 1985, EPA announced its intention to cancel all daminozide's food use registrations because test data indicated that the pesticide and its unavoidable metabolites posed an unreasonable risk to those who consumed treated foods. In 1985 EPA estimated that the lifetime cancer risks from the use of daminozide were startlingly high: one in a thousand, and for infants and children, perhaps, as high as one in one hundred. Since these risk levels were one thousand to ten thousand times greater than EPA's usual level of acceptable risk, Federal regulators would normally find them unacceptable.[22]

3. The 1985 EPA Decision Against Cancellation

Having proposed that Alar's registration be cancelled, the EPA referred the matter to its Scientific Advisory Panel (SAP) which reviews certain pesticide regulation decisions. The SAP concluded that the evidence presented by EPA was insufficient for a reliable risk assessment, and that, as a result, cancellation of the product's registrations was not warranted at that time.[23] The SAP indicated that it believed additional tests were necessary as there was insufficient data to conclude that Alar should be cancelled. EPA staff, in making their recommendation to cancel, had expressed similar concerns about the reliability of precise quantified risk estimates; however, they concluded that the weight of the evidence warranted cancellation.

Janet Hathaway, Senior Project Attorney, Natural Resources Defense Council, testifying at the May 15 hearing about the SAP's final report, noted that the SAP had said that primary studies of daminozide's oncogenicity, referred to as the Toth Studies, "do present concerns over the potential oncogenicity of daminozide. However, none of the present studies are considered suitable for quantitative risk assessment." (Hearing, Testimony of Janet Hathaway, p. 65) As Ms. Hathaway indicated, by 1985 the Toth data had been available for 8 years and the SAP apparently did

not understand why EPA had not requested, and why the registrant had not initiated in a more timely fashion, additional oncogenicity testing.

In the statement announcing its daminozide recommendation at the SAP meeting on September 27, 1985, the SAP said that "none of the present studies are considered suitable for quantitative risk assessment."[24] The written statement issued by the SAP on October 4, 1985, however, states that "the data available are inadequate to perform a qualitative risk assessment."[25] The differences between the terms quantitative and qualitative are potentially quite significant. Since EPA appears to give considerable weight to the recommendations of the SAP in reaching its policy determination, it is important that it know whether the SAP's objections were to the particular quantitative calculations derived from the studies or the broader implications of the quality of the studies' methodology. If the objections were to the entire qualitative assessment, then there would be a legitimate concern that all the data was inaccurrate and there was no need to act. If the objections were quantitative -- concerned with the precise risk estimate available, but not questioning the overall validity of the approach or the fact that the studies revealed a risk of cancer, then there would have been

good reason to consider some, even temporary, action to reduce risk immediately.

Citing the Scientific Advisory Panel's "qualitative" recommendation, the EPA announced in January 1986 that it was no longer proposing the cancellation of Alar. Alar was allowed to remain on the market, pending the submission of new toxicology and residue data from Uniroyal, its manufacturer.

EPA's policy has been to treat old chemicals differently from new chemicals; "a new pesticide is guilty until proven innocent, an old pesticide is innocent until proven guilty." (Hearing, Prepared Testimony of Dr. Charles Benbrook, p. 114) Since Alar is an "old" chemical, already registered, EPA believed it had to show that Alar might present an unreasonable risk, rather than requiring the registrant to show that Alar did not pose an unreasonable risk.[26] This procedure is unlike other statutes governing public health issues, or the apparent standard of FIFRA itself, in which the burden is on the product's proponent to show its safety. According to the SAP, the existing studies were not sufficiently reliable to meet this evidence threshold. Most disturbing to many Subcommittee Members was the fact that former EPA Assistant Administrator of Pesticides and Toxic Substances, Dr. John Moore, while he was Acting Deputy

Administrator of the EPA, stated a number of times that if Alar was a new chemical it would not be permitted to be registered.[27] Nonetheless, Dr. Moore concluded that he was unable to remove Alar from the market immediately. (Hearing, Testimony of Dr. John Moore, p. 44)

4. Cancellation Proposed -- 1989

In January 1989, EPA announced that based on the interim results of the new toxicology studies conducted by Uniroyal, it would initiate proceedings to cancel daminozide. These studies indicate that the concerns raised by the previous studies were correct, and that daminozide's metabolite UDMH is a potent animal carcinogen. According to established government-wide risk assessment policies, most potent animal carcinogens are considered "possible" or "probable" human carcinogens. EPA stated that formal action to cancel daminozide's registrations would begin as soon as the studies are submitted in final form by Uniroyal. The Agency estimated that cancellation proceedings could take a minimum of one year and as long as three or four years depending on whether the registrant chose to pursue the administrative and legal appeals available under FIFRA. Such appeals appeared likely in the Alar case because the registrant

continued to claim that Alar presented no real human health risk whatsoever.

Pursuant to FIFRA, continued use of a pesticide undergoing cancellation may continue until all administrative proceedings have concluded. Usually after the administrative proceedings are complete the cancellation will go into effect, even if the legal appeals continue. Only when EPA determines that an "imminent hazard" exists is a product's use terminated immediately,. If a pesticide is declared an "imminent hazard", EPA suspends its registration, barring all use pending the outcome of the cancellation proceedings, and then initiates the cancellation process. In the case of daminozide, EPA concluded that the estimated risks were sufficient to begin cancellation proceedings once the final data was formally presented, but that the risks were insufficient to declare daminozide an imminent hazard. (Hearing, Testimony of Dr. John Moore, pp. 44-45)

B. Subcommittee Review of EPA Regulation of Alar

The Senate Subcommittee on Toxic Substances, Environmental Oversight, Research and Development of the Committee on Environment and Public Works held a hearing to review procedures relating to the use of chemicals on food crops on May 15, 1989.

The Subcommittee focused primarily on the way the EPA has conducted its special review and re-evaluation of Alar. The story of EPA's handling of Alar provides significant insights into some difficulties with the federal statutes governing pesticide regulation, certain inefficiencies and disorganization at EPA, and the degree to which EPA has failed to proceed at a sufficient pace with reregistration and ensure that it has up-to-date, quality data. Some of the concerns may very well be addressed as the 1988 FIFRA amendments are implemented; others do not require legislative fixes but rather some changes in procedure inside the Agency. Furthermore, the hearing highlighted two specific concerns about the integrity and reliability of the EPA's scientific review, potential conflicts of interest on the SAP and significant disparities in the estimates of Alar residues on the most recent crop.

1. The Scientific Advisory Panel

Critical to the way in which the EPA has regulated pesticides is the role of the SAP, its membership, and its members' connections to the chemical industry. Subcommittee members learned prior to the hearing that the SAP, which is supposed to render an independent judgment on the safety of chemicals in our food supply, has a significant number of members who are active chemical industry consultants. Seven out of eight

members of the SAP that recommended against the EPA staff proposal to ban Alar in 1985 were paid consultants to the chemical industry or to organizations supported by the industry at the same time that they served on the panel. SAP members, however, are only required to recuse themselves from reviewing any chemical manufactured by a company from which they received money in the same year. The members can, however, accept funds from a particular company in the years before and after the year they review chemicals it produces. (Hearing, p. 57)

Christopher Wilkinson, one of the members of the SAP which reviewed Alar, apparently went on to do consulting work on Alar for Uniroyal, the company that makes Alar, just five months after leaving the SAP. Evidence in the Subcommittee's possession shows that he attended a meeting on Alar at EPA's offices as a consultant to Uniroyal. Another member of the Scientific Advisory Panel that recommended that Alar be allowed to remain on the market, Wendell Kilgore, was hired by a growers association after he left the panel to testify in favor of dinoseb [another chemical made by Uniroyal]. He had also been a member of the SAP which had advised the EPA not to cancel dinoseb. The Inspector General of the EPA has informed the Subcommitte that the Public Integrity divison of the Justice Department has decided not to prosecute these individuals. The Inspector General has not yet provided the Subcommittee with his final report on these members

of the SAP. Perhaps more importantly, however, their actions raise questions about the connections between SAP members and the companies whose products they are supposed to be reviewing in order to determine whether they are safe for the American consumer.

The fact that seven out of the eight members were paid consultants to the chemical industry raises serious questions about whether American consumers are getting the unbiased judgment on these matters which they are entitled to receive. Pursuant to the section of FIFRA, 7 U.S.C. Section 136(w)(d), which establishes the SAP, the National Institutes of Health and the National Science Foundation are to provide the Administrator with a list of nominees from which to select the panel members. The statute states that "[m]embers of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation for the disciplines of toxicology, pathology, environmental biology, and related sciences." It is noteworthy that, as of May 15, 1989, there are no public health experts or pediatricians on a panel which is responsible for making recommendations about pesticides that may have significant effects on the health of consumers and particular effects on children.

Although the SAP's opinion is not binding, its recommendations are highly valued by the EPA and, as in the case of Alar, are often relied on by the Agency. (Hearing, Testimony of Dr. John Moore, p. 55) The decisions of the SAP indicate that a certain bias may exist on the panel as it currently constituted. Dr. Moore testified that the SAP, since its creation, has never in his memory concluded that the EPA has underestimated the risk of a pesticide. Dr. Moore indicated, however, that the SAP has "commonly" told EPA that it has overestimated the risk of pesticides. (Hearing, Testimony of Dr. John Moore, p. 55)

The Subcommittee has also spoken with EPA staff scientists who have presented findings on pesticides to the SAP and who describe it as a "star chamber" in which the superior resources of the chemical companies work in their favor. The SAP reviews a number of chemicals at each of its meetings and EPA staff scientists must be prepared to reply to extensive questioning about all of them. Each chemical company, however, appears before the SAP with a battery of retained scientific experts who have worked solely on a particular chemical for years. Some EPA scientists maintain that this format and atmosphere contributes to the SAP so often deciding that EPA has overestimated risks. In their view, it is not a format for thoughtful scientific

exchange and does not result in a careful review of the reasons for the EPA staff recommendations.

2. Conflicting Data on Percent of Treated Apples

In February 1989 CBS Television's 60 Minutes broadcast the first of two reports on the dangers of Alar. In an attempt to calm consumer fears and show that there was actually very little risk, EPA released estimates of the percent of the apple crop with Alar residues. During the following months several independent investigations indicated that EPA's estimates had been significantly low. EPA has since raised its estimate slightly; however, its number is still far below that of the independent tests. It appears that EPA relied on industry figures while failing to do any independent analysis. EPA lost much of its credibility on the issue of food safety with the American public when it released conflicting and misleading data on Alar residues.

On March 16, 1989 EPA estimated in a widely-distributed press statement that only 5 percent of the crop was treated with Alar. In the May 1989 issue of Consumer Reports, the Consumer's Union reported that its independent tests indicated that 55 percent of fresh red apples and 22.5 percent of the processed

apple juice it tested had Alar residues above 0.3 ppm.[28] When CBS aired its second 60 Minutes report on Alar on May 14, 1989, it estimated, based on testing by an independent scientific laboratory it commissioned, that 32 percent of the apple crop was treated with Alar.

At the Subcommittee's May 15, 1989 hearing EPA made no mention of its earlier estimate that 5 percent of the apple crop was treated, and instead stated that 5-15 percent of the apple growers had used Alar. (Hearing, Prepared Testimony of Dr. John Moore, pp. 190-91) In response to questions from Subcommittee members about how EPA could have come up with the 5 percent figure in light of subsequent data, Dr. Moore testified that EPA's estimates are based on reports of sales that are filed with the Agency by registrants on a periodic basis. In this instance, in addition to that type of information which is generally available to EPA, he reported that the Agency also went to two marketing services and obtained their best estimate as to how much Alar had been used. EPA also relied on comments that had come from the field from cooperative extension agents and farmers. (Hearing, Testimony of Dr. John Moore, p. 48) On the basis of these estimates EPA came up with the original 5 percent number. EPA apparently did not attempt to independently test apple crop samples.

Dr. Moore testified on May 15 that since March 16 EPA's estimate has increased, "[r]ather than be down at 5 percent, I understand we're now closer to 15 percent. Certainly our estimate was low. ...We probably should have been more emphatic about the softness of the data by which we derived our estimate." (Hearing, Testimony of Dr. John Moore, p. 48). Dr. Moore did not explain why EPA's first estimate of 5 percent referred to the percent of the apple crop but the later number of 15 percent referred to apple growers.

On May 15, 1989 Members of the Subcommittee requested that both the Administrator of the Environmental Protection Agency and the Inspector General of the Environmental Protection Agency investigate the Agency's attempts to estimate crop exposure to daminozide. On August 29, 1989, the Members were informed by the Inspector General that the Agency had been inconsistent in its estimates of Alar use. (See letter to Senator Joseph I. Lieberman from Inspector General John C. Martin, Appendix #1) The Inspector General "could not obtain an adequate explanation for several anomalies in EPA's reporting." (Letter, p. 2) He was unable to explain why the numbers put forth to the public varied, why the figure was sometimes presented as the percentage of the crop treated with Alar and other times as the percentage of apple growers using Alar, and why the number was initially rounded to only 5 percent.

In a letter to the Subcommittee Chair, received September 12, 1989, despite Dr. Moore's acknowledgement of the weakness of EPA's data and the Inspector General's statements, the Administrator indicates that the Agency still believes its 5-15 percent number is accurate. The Administrator states that the original 5 percent estimate was a simplification of an estimate that 4-8 percent of the apple crop was treated with Alar, designed "to facilitate communication with the press and public." (Letter from Administrator William K. Reilly to Senator Harry Reid, September 12, 1989, Appendix #2) Furthermore, the Administrator states that EPA's numbers were consistent with those obtained in the independent studies, because they were done in the spring when apples are more likely to test positive and because they also show a decrease from previous years. The letter does not explain why Dr. Moore testified that 5-15 percent of the apple growers were using Alar as opposed to referring to the amount of the crop treated.

C. Subcommittee Members Introduce Legislation to Ban Alar

On May 18, 1989 members of the Subcommittee, joined by other members of the Senate, introduced legislation to ban the sale and use of Alar on food products. Although the involved members of the Subcommittee generally do not support legislative intrusion into the regulatory process on a pesticide-by-pesticide basis, in

this instance they believed the situation warranted immediate action. Growers and producers of apples and apple products were suffering significant financial losses because consumers, faced with conflicting information from regulators and other interested parties, understandably became afraid to consume apples. In order to save the apple industry from future harm and insure that consumers will not be exposed to any additional years of Alar-treated apples, members of the Subcommittee determined that it was necessary to initiate an immediate ban on Alar.

The legislation, S. 1061, introduced by three Subcommittee Members, not only banned the use and sale of Alar for food production, it also reduced the tolerance level for Alar to zero in order to insure that Alar residues could not legally appear on imported food products.

In direct response to the introduction of legislation to ban Alar, EPA and Uniroyal, the manufacturer of Alar, initiated discussions concerning a voluntary withdrawal of the pesticide from the domestic market. On June 2, 1989, Uniroyal agreed to voluntarily withdraw Alar from the United States market for food uses by halting sales and recalling all outstanding stock. Uniroyal, however, did not agree to cease selling Alar abroad. Although no longer available on the domestic market, Alar can still be sold abroad for food use and imported food products

containing Alar residues can be sold in the United States. Since over 50 percent of the apple juice concentrate sold in the United States is imported, Americans may still be exposed to Alar residues without their knowledge. Members of the Subcommittee wrote to EPA on June 22, 1989 to urge reduction of the tolerance level for Alar to zero in order to insure that no unnecessary additional exposure to Alar occurs.

On September 1, 1989 the Agency proposed a phased revocation of the food tolerances of daminozide. The proposal would lower the tolerance for raw apples from the current 20 parts per million (ppm) to five ppm on November 30, 1989. On November 30, 1990, the tolerance would be lowered to one ppm and on May 31, 1991 any detectable level of residue would be illegal. The tolerances for other commodities would be phased out over similar schedules.

D. Conclusion

The Subcommittee finds the handling of the Alar review troubling. Clearly there are numerous problems with the process by which EPA reviews the health risks of pesticides already on the market. While many of the problems may be attributable to the complexities of FIFRA and FFDCA, others appear to be due to the internal processes EPA has established. Some of these

internal procedures may be correctable without additional legislation.

The Subcommittee is very concerned about the integrity of the SAP. The EPA must act to insure that the panel members are not vulnerable to charges of conflicts of interest. The American people must be able to trust their recommendations. Furthermore, EPA must obtain clear explanations of the basis for all SAP decisions. Since the Agency has repeatedly cited the SAP's rejection of the Toth studies (the studies relied on by the EPA staff who recommended cancellation) as the basis for not cancelling Alar in 1985, the Subcommittee is disturbed by the inconsistencies which exist between the SAP's analysis of these studies as stated at the public meeting and the findings as presented in the written report published a week later. Given the degree to which the Agency appears to rely on the SAP's recommendations, particularly in the case of Alar, it is critically important that the SAP's views be clearly set forth.

The Subcommittee is also concerned about EPA's internal procedures for estimating how much of a given crop is treated with a pesticide. These estimates become very important when they are widely publicized in order to reassure the public that the food supply is safe. Members of the Subcommittee were particularly disturbed by the conflicting estimates provided by

22-520 - 89 - 4

EPA about the percentage of the apple crop which had been treated with Alar. If nongovernmental groups are able to obtain relatively quickly estimates of the percent of the crop treated based on actual, independent testing, it would appear that the FDA and the EPA should be able to do so as well. Certainly if the Agency is unsure as to the accuracy of its numbers, it should not have released them without any caveats.

IV. Other Failures in EPA Pesticide Regulation

In addition to the testimony at the May 15, 1989 hearing about Alar and EPA's failure to make significant headway with reregistration and the conflicts caused by the Delaney Paradox, the witnesses raised a number of other important pesticide regulation problems.

A. EPA's Failure to Protect Us From The Most Dangerous Chemicals

Dr. Benbrook presented information which emphasized the fact that EPA has been unsuccessful at removing the most dangerous pesticides from the market. EPA now has established approximately 8,500 distinct tolerances. Of all these pesticides

one group, fungicides, account for over 50 percent of the estimated risk in fresh foods and almost 80 percent of the risk in processed foods. (Hearing, Testimony of Dr. Charles Benbrook, p. 21) Of the 10 most dangerous pesticides, nine are fungicides and all are old pesticides. (Hearing, Testimony of Dr. Charles Benbrook, p. 22) It would appear that by cancelling these relatively few pesticides, EPA could eliminate a large percentage of the risk from chemicals in our food. However, because there are not adequate replacements for at least some of these fungicides, under EPA's risk-benefit analysis they cannot be easily removed from the market. As Dr. Benbrook noted, EPA does not have the ability to reduce the risk from these chemicals without going through the lengthy process for reregistering and tolerance-setting. (Hearing, Testimony of Dr. Charles Benbrook, p. 22)

B. Setting Tolerances For Processed Foods

The fact that many tolerances are based on outdated data and no longer reflect the actual level of use on raw produce, means that many pesticides which should have Delaney tolerances may not. In some of these cases the older tolerance levels, established based on information which did not reveal risks which are now known, have meant that the Agency has not yet had to confront the Delaney Clause and its prohibition against granting

a tolerance for those pesticides or their metabolities which concentrate in processed food and have been identified as animal or human carcinogens.

If EPA does not reassess tolerances in accordance with the most recent information on health risks and growers' application practices, then we run the risk that consumers may be exposed to unintentionally, unnecessarily high levels that may be unsafe. Furthermore, if the tolerance is outdated and, therefore, too high, then the consumer runs the risk that the pesticide will appear at this higher, yet legal, level on some foods.

C. When Should EPA Invoke The Imminent Hazard Provision

Although EPA has the authority to immediately suspend the use of a pesticide if it is determined to be an imminent hazard, it has rarely used this provision and maintains that proving imminent hazard involves "rather demanding tests." (Hearing, Testimony of Dr. John Moore, p. 45). EPA has maintained that "the risks that are associated with Alar's use during the period of cancellation does not fit the statutory requirements that we think need to be met in order to invoke suspension." (Hearing, Testimony of Dr. John Moore, p. 44)

In other contexts and under other statutes, however, EPA has applied the imminent hazard language in a much broader fashion allowing the Agency to act more quickly when necessary to protect the public. Section 106 of Superfund, Section 7003 of RCRA, and Section 504 of the Safe Drinking Water Act all contain the imminent hazard language. Under each of these provisions, the EPA has encouraged the courts to accept a broad interpretation of "imminent hazard" and the courts have generally accepted that interpretation. In giving the term "imminent hazard" a broad definition under CERCLA, courts have noted that both RCRA and the Safe Drinking Water Act define "imminent hazard" as covering a current contamination which could cause ill-health effects after a latency period. (United States v. Conservation Chemical Co., 619 F.Supp. 162, 192 - 194 (D.C. Mo. 1985)) Courts have noted that "the word imminent does not require proof that the harm will occur tomorrow..." (619 F. Supp. at 194) and have found endangerment to be "imminent" "if conditions which give rise to it are present even though the actual harm may not be realized for years." (B.F. Goodrich Co. v. Harold Murtha, Civil No. N-87-52 (PCD) (D.C. CT 1988)) Since additional exposure to a cancer-causing pesticide increases one's risk of cancer, continued exposure during a potentially lengthy cancellation period would appear to be an imminent hazard although it causes a harm which may not be manifest for years.

D. Review of Synergistic and Cumulative Effects

There are 50,000 agricultural chemicals used in America today and while few have been fully tested alone, there is no requirement that any of these chemicals be tested in the combinations in which they are most often used or the combinations to which individuals are most often exposed. Furthermore, EPA does not monitor the cumulative effects of exposure to a variety of pesticides which are probable carincogens or neurotoxins on the food we eat. (Hearing, Prepared Testimony of Janet Hathaway, p. 239) Scientists have concluded that an individual who smokes cigarettes is at much greater risk from exposure to asbestos than one who does not, because of the synergistic effect of the combination of the two toxins.[29] Similarly, there are certain pesticides which are used together potentially amplifying their deleterious effects. In addition, pesticides which are not actually mixed together in the field may appear in combinations on individual food products and in our diet as a whole.

A report prepared by the United States Public Interest Research Group (USPIRG) in April 1989, "A Study of Carcinogenic Pesticides Allowed in 16 Foods and Found in Water: Guess What's Coming To Dinner", found that a sample one day adult diet

consisting of three meals may contain 54 different pesticides that cause cancer in animals or humans. The report selected 16 commonly eaten foods and found that all of them are allowed to contain numerous carcinogenic pesticide residues. The report notes that while an individual pesticide may be well below the tolerance level, the risk from exposure to all pesticides which may appear in our diet is unknown.

The EPA does not calculate the cumulative or synergistic effects of exposure to a variety of food-use pesticides.[30] For example, the risk of daminozide is calculated by the EPA as if it was the only pesticide to which the individual was exposed, although pesticides such as Captan and EBDCs are also used on apples. We do not know if use in conjunction with other pesticides magnifies the risk to public health from a pesticide like Alar, nor do we know to what degree the combination of chemicals on any given food product increases the risk to our health.

Other exposures to pesticides, particularly from drinking water, as well as from the air and the workplace, are not currently factored into the EPA's regulation of pesticides in food. In determining its tolerance levels, associated with a specific registration, EPA assumes there is no other exposure to

the pesticide except on the food in question. A June 1987 Department of Agriculture report estimated that agricultural pesticides now threaten the ground water supply of 50 million rural Americans. EPA has said that it would begin taking into account drinking water exposure when examining tolerance levels.

E. Protecting Sensitive Subpopulations

Several witnesses testified that FIFRA fails to place sufficient emphasis on protecting sensitive subpopulations, such as infants, children, and pregnant women, which are at greater risk from pesticide exposure. (Hearing, Testimony of Ralph Nader, p. 7; Testimony of Dr. Steven Markowitz, p. 36; Prepared Testimony of Janet Hathaway, pp. 235-6) Many tolerances were set using consumption data from the early 1960's, reflecting the eating patterns of the average 18 year old, 165 pound male. The EPA Tolerance Assessment System (TAS) created in 1985 replaces EPA's older data base which relied on food consumption data from a 1966 food consumption survey. The old data base did not distinguish among the different eating habits of various subpopulations. The TAS, based on a 1977-1978 food consumption survey, contains information on the consumption of 376 food types and can provide data on a range of subpopulations.[31] Although the data in the TAS can be broken down by subgroup and is more

recent than that in the previous data base, it is already 12 years old and may not reflect today's consumption patterns.

The NRDC Report "Intolerable Risk: Pesticides in our Children's Food" concludes that children are being harmed by the very fruits and vegetables that are necessary for them to grow healthy and strong. Fruits and vegetables, a significant part of a child's diet, "routinely, and lawfully, contain amounts of pesticides, which pose an increased risk of cancer, neurobehavioral damage, and other health problems." [32] The NRDC maintains that the EPA has not taken sufficient steps to protect children from the chemicals in their food and has failed to account for the fact that children consume much higher quantities of fruits and vegetables relative to their body weight than do adults.

Fruit, according to the NRDC analysis, is 34 percent of a preschooler's diet but only 20 percent of an adult's diet.[33] The average toddler consumes 31 times more apple juice based on relative weight, than the average adult woman.[34] Since pesticide tolerance levels were calculated based upon adult consumption and different tolerance levels are not established for different population subgroups, it would seem that children are exposed to residue levels designed for adults despite the

fact that they consume more fruits and vegetables and weigh less. Not only are infants and children exposed to proportionately more pesticides due to their diet and their weight, they also may be physiologically more vulnerable to the potential toxic effects of these chemicals because their immune system is less developed, they are growing rapidly, and have a longer time available for any ill effects of chemical exposures to occur since they are young. (Hearing, Prepared Testimony of Dr. Ronald Wood, p. 163; Intolerable Risk, pp. 103-33; Testimony of Dr. Deborah Prothrow-Stith, Commissioner, Massachusetts Department of Public Health, Presented to the Subcommittee on Children, Family, Drugs and Alcoholism of the United States Senate Committee on Labor and Human Resources, March 16, 1989, p. 2)

The results of the NRDC study differ from EPA's assessment of the risks of UDMH, a metabolite of daminozide. The NRDC report claims that the risk of UDMH as determined by EPA is grossly underestimated, and that it in fact surpasses EPA guidelines of acceptable risk by a factor of approximately 240.[35] Altogether, the report concludes that, based on the actual residues of eight pesticides and their metabolites found in 27 different types of fruits and vegetables, the average excess lifetime risk of cancer for children is approximately 250

to 280 times greater than what EPA accepts as an acceptable risk.[36]

The EPA maintains that its current process for setting tolerances adequately protects children. Its calculation of composite average lifetime risk takes into account children's proportionately greater exposure to certain foods and, therefore, to certain pesticide products. Dr. John Moore has testified that the scientific data as to whether children are more sensitive to pesticides is "limited and inconclusive;" however, the Agency has contracted with the National Academy of Sciences to study the potential greater risks to children from pesticides. (Prepared Testimony, Dr. John Moore, Acting Deputy Administrator, U.S. Environmental Protection Agency, Subcommittee on Children, Family, Drugs and Alcoholism, United States Senate Committee on Labor and Human Resources, March 16, 1989, pp. 4-6)

As noted above a number of those who have studied the risks to children have concluded that the children are at a greater risk and that, in some cases, the risks are unacceptable. Despite EPA's reassurances, in May 1986, the Commonwealth of Massachusetts adopted regulations to further limit the amount of daminozide in processed apple products, phasing out all detectable levels by October 1988. Massachusetts concluded that

children were at a greater risk from daminozide and UDMH than was the general population. (Prepared Testimony of Dr. Deborah Prithrow-Stith, Commissioner, Massachusetts Department of Public Health, Subcommittee on Children, Families, Drugs and Alcoholism, United States Senate Committee on Labor and Human Resources, March 16, 1989, pp. 1-2) The Subcommittee is very concerned about the potential of a greater risk to children from pesticides. We look forward to the report from the National Academy of Sciences on this question and we strongly urge the EPA to place a particular emphasis on determining whether changes need to be made in the way it regulates pesticides to insure that children or other sensitive sub-groups are not exposed to this excessive risk.

F. Review of Neurotoxic Effects

Testimony regarding regulation of pesticides for potential neurotoxic effects was also reviewed by the Subcommittee. The NRDC report claims that EPA has largely ignored the potential neurotoxic effect of certain pesticides on infants and children. NRDC estimates that at least 17 percent of the preschool population is exposed to residues on raw fruits and vegetables from eight neurotoxic organophosphate insecticides which are above levels considered acceptable by EPA. (Hearing, Prepared Testimony of Janet Hathaway, p. 213)

Dr. Steven B. Markowitz, Deputy Director, Division of Environmental and Occupational Medicine, Mt. Sinai School of Medicine, New York, N.Y., testified that there are two classes of pesticides, organophosphates and carbamates, for which the principal site of toxicity is the nervous system. These pesticides replaced DDT and chemically similar pesticides as they were banned or otherwise removed from use during the past 20 years. Dr. Markowitz, referring to the NRDC study, stated that three to ten million pre-school children receive excessive exposure to organophosphates on a daily basis. He testified that there have been no studies of children which test for neurological or neuropsychological deficits caused by pesticides. Scientists, therefore, must rely on animal data and occupational studies in order to assess the effects on children's health. (Hearing, Testimony of Dr. Steven Markowitz, p. 35)

According to Dr. Ronald W. Wood, Research Associate Professor of Environmental Medicine, New York University Medical Center, representing the American Psychological Association, the EPA assumes that "protecting against other effects will protect against neurotoxicity. We think this is a very dubious assumption at best for agents that are designed to affect the central nervous system." (Hearing, Testimony of Dr. Ronald Wood, p. 37) Under current EPA requirements, there is only limited evaluation of the effects of pesticides on the central nervous

system. The only neurotoxic test currently required is the hen test, which is a non-mammalian test for one particular type of injury. The test is used to determine only acute effects such as immediate paralysis or death not chronic or longer term effects. In addition, according to Dr. Wood, there are some crude cage-side observations of the condition of animals, and a "cursory, and... inadequate examination of the brain." (Hearing, Testimony of Dr. Ronald Wood, pp. 37, 41)

EPA does not require tests for the chronic neurotoxic effects that might be caused by lower levels of exposure to pesticides. Dr. Wood testified that none of the techniques now employed by the drug industry to determine the neurotoxic effects of new drugs before they are released for human consumption are utilized by the EPA. (Hearing, Testimony of Dr. Ronald Wood, p. 41) The hen test, which only determines the acute effects of exposure to pesticides (i.e. whether exposure causes paralysis or death) does not provide information on the long-term neurotoxic effects of chronic low-level exposure. (Hearing, Testimony of Dr. Ronald Wood, pp. 37, 41) Testing for chronic low-level exposure is important because, as Dr. Markowitz testified, this exposure will not produce acute poisoning, but may cause learning disabilities or other problems with mental processes. (Hearing, Testimony of Dr. Steven Markowitz, p. 35)

Dr. Markowitz also noted that tolerance levels should be reduced because children are not exposed to a single pesticide at a time, rather they are exposed to a whole class of pesticides, such as organophosphates, which may act together to produce neuropsychological deficits. (Hearing, Testimony of Dr. Steven Markowitz, p. 36) In addition, Dr. Wood testified that not only do we need to improve testing on the effects of consuming food treated with neurotoxic pesticides, we must also improve government surveillance of the workers who manufacture, mix, and apply these chemicals. (Hearing, Testimony of Dr. Ronald Wood, p. 37) EPA is currently funding a study at the University of Claifornia at Berkeley on workers' exposure.

EPA does not currently require pesticide manufacturers to provide data on the possible neurotoxic effects of low-level chronic exposure to pesticides. Under TSCA EPA has developed more recent neurotoxicity standards, and these standards should be adopted as part of the FIFRA data requirements. (Hearing, Testimony of Dr. Ronald Wood, p. 37)

G. Captan

The Subcommittee is also concerned about the recent EPA decision on the pesticide Captan. Dr. Benbrook, in his testimony, cited the Captan decision as yet another example of

EPA's disparate regulation of old and new pesticides. (Hearing, Testimony of Dr. Charles Benbrook, p. 33) A key problem with the Captan decision and with EPA's implementation of reregistration is that it postpones until some as yet undetermined time any adjustments in tolerance levels as part the eventual final reregistration package. (Hearing, Testimony of Dr. Charles Benbrook, p. 32)

By 1980 the National Cancer Institute had determined that Captan was an animal carcinogen. EPA initiated its special review in 1980.[37] Yet, in 1989 most Captan uses continue and it commonly appears on the food we eat. EPA recently determined that it is necessary to reduce our exposure to Captan. The Agency has proposed to eliminate Captan from use on minor fruits and vegetables including leeks and quince, but allow it to remain on strawberries, cherries, and grapes. EPA cancelled the tolerances of 45 uses of Captan on some minor crops and on some major crops on which very little is used.[38] As Dr. Benbrook noted "By focusing on those uses where not much Captan is used and really leaving untouched most of the major uses of the chemical, obviously the decision has had modest impact on actual risk." (Hearing, Testimony of Dr. Charles Benbrook, p. 32) Since children, in particular, eat many more strawberries, cherries and

grapes than they do leeks and quince, this decision certainly reduces their exposure very little, if at all.

In its decision, EPA indicated that the actual residue data suggested that the level of Captan on major crop uses was significantly lower than the level of risk suggested by the published tolerance. EPA did not, however, at the time of the Captan decision, lower any of those tolerances even though it knew that the actual residue levels were an order of magnitude, a factor of 10, lower. (Hearing, Testimony of Dr. Charles Benbrook, p. 32) By reducing its use on minor use crops, foods which few Americans consume regularly, EPA has not significantly reduced the risk from exposure to Captan. Furthermore, by allowing the tolerance level to remain high, even though actual residue levels are much lower, EPA runs the risk that Captan may still appear at legal but much higher than acceptable levels in our food.

V. CONCLUSIONS/RECOMMENDATIONS

As the oversight subcommittee, it is this subcommittee's responsibility to monitor the EPA and ensure that it is doing its job. Based on the May 15 hearing and background research, the subcommittee is concerned about the way the EPA has conducted reregistration and its overall program for regulating pesticides

in our food. While a number of our witnesses expressed concern about FIFRA, the problems cannot be attributed solely to inadequacies in existing statutes, but must also be attributed to the way in which EPA has carried out its statutory mandate. We are faced with a regulatory program that is not working; it is not protecting those who are at risk.

A. Review of Top Ten Most Dangerous Pesticides

Perhaps the most significant problem with pesticide regulation today is the number of "old" pesticides on the market. The Agency must speed up the reregistration of pesticides which were first registered 20 and 30 years ago. The National Academy of Sciences, in its report Regulating Pesticides in Food, states that the major contributors to total risk are 10 to 12 primarily old pesticides (see chart, Appendix #3). Dr. Benbrook testified that cancelling these 10 or 12 pesticides "would eliminate a very large portion of the risk." (Hearing, Testimony of Dr. Charles Benbrook, p. 25) The EPA maintains that several of these pesticides have been or are in the process of being cancelled and that for others the risks are not as high as the chart indicates. (Hearing, Testimony of Dr. John Moore, p. 46) Whether or not these particular 10 present the highest risk, as currently assessed, it is evident that there are a number of "old" pesticides which have now been shown to present significant risks

and the EPA should focus on developing a schedule for the reregistration and reassessment of tolerances for these pesticides.

B. The Scientific Advisory Panel

As described in the Alar story, the Subcommittee has some concerns about conflicts of interest and the appearance of conflicts of interest on the Scientific Advisory Panel (SAP). The fact that 7 out of the 8 members of the Alar SAP did consulting for the chemical industry while they served on the SAP certainly gives the appearance of bias. EPA must re-examine its conflict-of-interest regulations to ensure that the American people are guaranteed scientific judgments made by a clearly unbiased panel.

Furthermore, the Subcommittee is concerned about the fact that in the past there have not been either pediatricians or public health professionals on the panel which is advising EPA about the potential health risks of pesticides. Particularly at a time when there are concerns about the special risks to children, it would appear appropriate to have pediatricians with the relevant background on the SAP. EPA should request that NSF and NIH nominate pediatricians and public health professionals for the SAP. The Agency may also want to consider expanding the

SAP to ensure that all relevant disciplines are adequately represented.

C. Suspension and Imminent Hazard

The Subcommittee has concluded that EPA has not used its authority to suspend pesticides due to imminent hazard in such a way as to protect consumers from risk while it embarks on its often lengthy cancellation process. Alar is a perfect case in point. EPA must re-examine its interpretation and application of its suspension power. If EPA concludes that it is impossible to stop the use of pesticides like Alar, when there are troubling risk estimates based on a large volume of data not all of which may be able to "prove" that an "imminent hazard" exists, then it should forward amendments to Congress which would allow it to do so.

The concept of suspension should be broadened, to allow EPA to remove, perhaps temporarily, a pesticide from use once dangerous levels of estimated risk has been uncovered. At the moment, there is no interim regulatory authority which would allow EPA to reduce or suspend without showing imminent hazard. If the initial data on a pesticide is problematic, EPA is unable to reduce risk by limiting certain registrations or otherwise decreasing the use of a pesticide while it gathers additional

information. EPA should have interim authority to reduce tolerances to safer levels, cancel all uses, some uses, or place restrictions on use or application methods so as to reduce risks and protect the public while additional research is performed or the cancellation process is begun.

Unless the EPA determines there are very high benefits associated with continued use of a pesticide, the Agency should take clear and immediate steps to reduce all tolerances to or below a negligible risk level. In those circumstances when EPA is concerned that alternative pesticides may pose similar or even greater risks, tolerance levels covering all potentially hazardous pesticides registered for use on the particular crop should be reduced concurrently over at most three years to negligible risk levels or below.

D. Overall Plan and Schedule

1. Ensuring Completion of Reregistration

At this point EPA is only reregistering active ingredients. EPA still must apply decisions reached on each of these active ingredients to some 20,000 - 35,000 individual pesticide products containing the active ingredients. Currently, there is no clear or convincing plan developed to complete this process.

EPA does not have the management systems in place to provide accurate data on the status of the pesticide reregistration program. It is unable to determine the status of any given chemical in the reregistration process and cannot determine with any speed what data is outstanding on a chemical. EPA must devise a system for tracking the reregistration process. The Agency must be able to determine immediately that a data call-in has not been complied with and take speedy action.

At the moment it may be to a company's advantage to delay in complying with data call-ins, if their pesticide is allowed to remain on the market until the data is in. Despite the fact that EPA has the authority under Section 3(2)(B)(iv) of FIFRA (7 U.S.C. Section 136a(2)(B)(iv)) to suspend a registration if the registrant delays or fails to present required additional data, GAO testified that as of 1986 EPA could not complete reassessment of 84 of the 92 interim registration standards because data was missing or invalid. (Hearing, Prepared Testimony of Peter Guerrero, GAO, p. 124) When a registrant does not submit data in a timely fashion, EPA should act quickly to suspend the registration of the pesticide at issue.

2. Keeping Registrations Current

EPA needs to keep registrations current. Ongoing advancements in science and technology continually improve our ability to evaluate pesticides and, therefore, registrations must be updated on a regular basis. In addition, new types of data requirements may be identified after a pesticide is registered, such as neurotoxicity data. The EPA has not specified how "new" pesticide registrations will be kept current, and whether, in fact, it is feasible within the Agency's existing resources and mandate to insure that periodically all registrations are updated. EPA has also not explained why they have not used Section 6(a) of FIFRA (7 U.S.C. Section 136d(a)), which allows the Agency to cancel pesticide registrations at the end of five years unless the registrant requests a continuation, to keep pesticide registrations current.

E. Resolve Conflicts Between Risk-Benefit Analysis and Delaney Clause

Under current EPA policy when a manufacturer applies for a registration for a new chemical, it must provide the most recent, toxicologically sophisticated data and is subject to very strict standards. Generally, even a very low level risk of oncogenicity will, according to EPA, prevent a chemical from being registered. However, for perhaps the very same use, there may be an older

product on the market with a much higher risk level. Because there is no registered alternative for the high risk pesticide, EPA evaluates its associated benefits as high and is unwilling to remove it from the market.

Congress must re-evaluate the Delaney Clause to determine whether it provides the most effective protection to consumers or whether it prevents safer chemicals from coming on the market while allowing more dangerous ones to remain on the market because no replacements are available. It must determine whether a negligible risk standard, with a specific definition of negligible risk so that the Agency does not have too much discretion, would be more appropriate.

According to the National Academy of Sciences, applying a consistent risk-based, negligible risk standard to new and old pesticides, to residues in fresh and processed foods could bring about approximately a 90 percent reduction in risk by allowing approval of new pesticide alternatives to replace the old. Furthermore, when risks get above a certain level, EPA should not be concerned about benefits and should act immediately.

F. Neurotoxicity Testing

The EPA must move much more vigorously on premarket testing of chemicals for neurotoxicity. To properly evaluate a pesticide for neurotoxicity, a three-part approach should be developed. Thorough testing should be required prior to registration or reregistration of these chemicals, including a range of tests for both acute and chronic low-level exposures. Secondly, pesticide residues on foods should be monitored more closely so that we know more precisely the amount of potentially neurotoxic chemicals to which different subpopulations are exposed. Under the existing FDA program approximately only 50 percent or fewer of pesticides are detected by the tests currently used. Finally, EPA should calculate allowable tolerance levels recognizing that children are not exposed to a single pesticide at a time, but rather are exposed to a whole array of pesticides which may have cumulative and/or synergistic effects. Being exposed to a number of pesticides in the same class may be particularly harmful, for instance, the organophosphates which work together to produce neuropsychological deficits.

G. Shorter Review Time for Certain Chemicals

Once the Agency makes a determination that action should be taken against a registered chemical, it should have the ability to move forward and effect cancellation in a reasonable period of time. (Hearing, Testimony of Dr. John Moore, p. 45) EPA has

informed the Subcommittee that it is now examining a number of changes in FIFRA which would address some of the problems revealed by the Alar controversy.

One proposal is to eliminate the middle step of the administrative hearing, and rely instead on notice and comment rulemaking which is less time-consuming. Under this proposal when a final decision is made by the Agency, then any party which objects may go directly to the Federal courts, eliminating a potentially time consuming middle step. (See Hearing, Testimony of Dr. John Moore, p.43.)

A second proposal is the development of a more permissive standard for invoking suspension than is in the current statute. This proposal would allow the Administrator more discretion to suspend a chemical even if the imminent hazard standard as currently defined has not been met. The Agency has indicated they would like interim authority to suspend while reviewing the data on a pesticide which appears to present a significant risk.

A third suggestion is to make registrations valid for a fixed period of time, for instance nine years. Under this sunset provision, if the manufacturer wanted to continue marketing the product, it would be required to secure a new registration.

H. Tolerance Levels Should Equal Safe Exposure Levels

Tolerances need to be set at levels which are safe. Given that tolerances are set intentionally high to account for widely varying conditions of potential use and that none of the older food-use tolerances have been reassessed, it is not reassuring to hear EPA attempt to calm public alarm by saying that it thinks the risk is acceptable because the tolerance level is not being exceeded. We know that many of the tolerances for older chemicals were set long before current scientific data was available, and are, in effect, often based on data now considered unreliable and inadequate to be the basis for a thorough safety evaluation. As the new data is developed, the legal residues should be lowered to reflect the often large degree of uncertainty underlying the current tolerance and should better approximate realistic exposure levels (either as consumed or as treated on the farm). More realistic tolerances will help to ensure that all growers are using the chemical safely, prudently, and minimally. Consumers should not be subjected to the risk that a few growers may exceed the usual level of residues and approach much higher, albeit legal, limits.

I. Setting Tolerances Based on Health Effects and Effects On Subpopulations

As noted above, existing tolerance levels often do not reflect actual levels at which use is safe. EPA will be collecting new data on the health and environmental effects of pesticides as a result of the 1988 amendments to FIFRA, but it is not clear when or whether EPA will use this data to reestablish tolerances for major food use pesticides at new levels which will truly protect the public health. EPA should use the most current information on dietary consumption and the risks to special subpopulations to set all new tolerances and should revise all existing tolerances with this more accurate data. The revision of tolerances should begin as soon as the new data is available to the Agency.

EPA should ensure that the most exposed and most vulnerable members of society, infants and children are adequately protected from pesticide residues. EPA's attempt to calm public fears by referring to the average diet of an American adult is particularly inappropriate for preschoolers. Pesticide limits should be set to protect children and other "non-average" eaters. EPA should revise existing tolerances and establish new tolerances, based on the specific dietary intake of preschoolers

and other especially vulnerable or highly exposed subgroups of the population.

For those pesticides which are a particular risk to infants and children because of their eating habits and special susceptibilities, EPA should rapidly set legal limits which ensure that any residues of these chemicals persisting in our food supply do not present a hazard to preschoolers. It should take no longer than one year from the time the Agency receives updated data for EPA to set new, protective tolerances for the chemicals. If the Agency requires additional funds or authority in order to protect our children, it should so inform the Congress.

J. Cumulative and Synergistic Effects

EPA must ensure that cumulative exposure to a variety of pesticides in foods, in drinking water and in the air of our homes are considered when tolerance levels are set. When EPA sets an individual tolerance level, EPA calculates the risk as if people were exposed only to a single pesticide from a single food at any given time. EPA should consider the combination of pesticides consumers are exposed to in their diets and the fact that consumers are exposed to many of the same pesticides in their drinking water and in their homes.

K. Inert Ingredients

EPA must begin to examine the use of dangerous inert ingredients in pesticides and factor the risk from the inerts into the risk assessment for the pesticide. Inerts which are hazardous should have their own tolerances.

L. Detection of Residues in Food

Pesticides should not be used on food if FDA cannot readily detect their residues in food. EPA should require that manufacturers of pesticides used on food develop practical methods for detecting pesticide residues. At this time only 50% of pesticide residues can be detected by the multi-residue tests done by the FDA. Many, if not most, pesticide residues (such as EBDCs) can only be detected by individual tests; however, the FDA does not routinely test produce for those pesticides not detected by a multi-residue test method. For those pesticides which cannot be detected by multi-residue tests, FDA should establish a plan for regular, frequent testing.

The Subcommittee looks forward to EPA's response to these proposals and will work with Agency, wherever possible, to improve the pesticide regulation program.

FOOTNOTES

1 Congressional Research Service(CRS) Report, Pesticide Regulation: Legislative Debate About FIFRA in 1986 (May 11, 1987), p. 1.

2 CRS Reports, (May 11, 1987), p. 2.

3 Paul G. Hayes, "Pests and Perfection" The Milwaukee Journal Sunday Magazine (August 27, 1989).

4 CRS Report (May 11, 1987), pp. 2-3.

5 National Research Council, Alternative Agriculture, p. 44.

6 National Research Council, Regulating Pesticides in Food, pp. 142, 157-58.

7 National Research Council, Alternative Agriculture, p. 38.

8 National Research Council, Regulating Pesticides in Food, p. 165.

9 Congressional Research Service (CRS) Report, Apple Alarm: Public Concern About Pesticide Residues in Fruit and Vegetables (March 10, 1989), p. 4.

10 CRS Report (March 10, 1989), p. 4.

11 CRS Report (March 10, 1989), p. 4.

12 CRS Report (March 10, 1989), p. 4.

13 CRS Report (March 10, 1989), pp. 4-5.

14 CRS Report (March 10, 1989), p. 5.

15 As discussed in Section II(B), the Delaney Clause requires that no tolerance be granted for pesticide residues which concentrate in processed food if the pesticide has been shown to induce cancer in animals or people. The Delaney Paradox arises from the difficulty

of reconciling this zero risk standard for processed food with the more flexible standard for tolerances on raw food. The ramifications of this paradox are discussed in this section.

16 A metabolite is a breakdown product which results when a pesticide is ingested or processed.

17 National Research Council, Regulating Pesticides in Food, pp. 31-2.

18 National Research Council, Regulating Pesticides in Food, p. 89.

19 National Research Council, Regulating Pesticides in Food, p. 83.

20 Originally chemicals were those registered before 1972; however, since reregistration did not actually begin in 1972, the National Acacdemy of Sciences defines an old chemical as on registered before 1978. National Research Council, Regulating Pesticides in Food, p. 85.

21 CRS Report (March 10, 1989) p. 7.

22 CRS Report (March 10, 1989), p. 7.

23 CRS Reports (March 10, 1989), p. 7.

24 Transcript of September 27, 1985 Scientific Advisory Panel meeting, p. 12.

25 Statement issued by Scientific Advisory Panel on Alar, October 4, 1985, p. 2.

26 See Section II(C)(1) of this report.

27 CBS 60 Minutes, February 26, 1989.

28 Consumer Reports at 288-89, May 1989

29 USPIRG, A Study of Carcinogenic Pesticides Allowed in 16 Foods and Found in Water: Guess What's Comming To Dinner? (April 1989), p. 3.

30 USPIRG, p. 3.

31 National Research Council, Regulating Pesticides in Food, p. 57.

32 Natural Resources Defense Council, Intolerable Risk, p. 1.

33 Intolerable Risk, p. 7.

34 Intolerable Risk, p. 8.

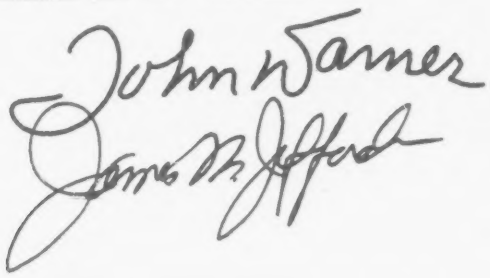
35 Intolerable Risk, p. 5.

36 Intolerable Risk, p. 68.

37 National Research Council, Regulating Pesticides in Food (1987), pp. 201-2.

38 "Captan; Intent to Cancel Registrations; Conclusions of Special Review; Notice of Final Determination" Federal Register, Vol. 54, No. 36 (Friday, February 24, 1989), pp. 8116-17.

ADDITIONAL VIEWS OF MR. WARNER AND MR. JEFFORDS



The Senate Environment and Public Works Subcommittee on Toxic Substances, Environmental Oversight and Research and Development has spent a considerable amount of time this year reviewing the Environmental Protection Agency's (EPA) pesticide regulatory program. Perhaps the most significant force behind our efforts was the controversy which surfaced in February concerning daminozide (Alar). The Subcommittee has now issued its findings in the attached report, and I must confess that my feelings with regard to this report are mixed.

I signed the Subcommittee report because I believe that the Congress has a responsibility to further review and ultimately revise the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In addition, I believe it is imperative that the American consumer have confidence not only in the safety of our food supply, but also in the Government's ability to effectively implement its pesticide regulatory program. I believe we can achieve this goal by revising FIFRA in a constructive fashion that will strengthen the EPA's ability to effectively implement the pesticide regulatory program. The Subcommittee report recognizes these points.

I find it somewhat disturbing, however, that the Subcommittee report focuses so much criticism on EPA's handling of the Alar controversy. I believe that EPA was as much a victim of the existing FIFRA statute as were the consumer and the Nation's fruit growers. In fact, the EPA worked very closely with me and other members of the Subcommittee in crafting the legislation, S.1061, which ultimately led to the agreement reached between EPA and the Uniroyal Chemical Company whereby Uniroyal voluntarily halted sales of Alar.

In addition, at the request of myself and Senators Reid and Lieberman, the EPA recently took action to reduce the tolerance level for daminozide residues to zero. This action will give the American consumer confidence that this chemical will not continue to reside in food products imported into this country. The EPA is to be commended for this action.

As I stated during the Subcommittee hearings on May 15, 1989, much of the fault for the Alar controversy rests on Congress for past actions. We have a law in place that does not meet modern standards. It is the business of this Subcommittee to identify the problems in FIFRA and to help provide the solutions.

I am confident that with the help of the Administration, the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and members of industry we will be able to make the necessary

revisions to FIFRA to avoid such a serious situation in the future. In fact, I anticipate the Administration will soon forward to Congress a comprehensive food safety proposal which will include amendments to FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA).

The cooperation and bipartisanship demonstrated during the Alar controversy will be an essential ingredient to the success of the work that lies ahead for the Subcommittee and the Administration.

With respect to the conclusions and recommendations contained in the Subcommittee report, I have mixed feelings here as well. I have outlined point by point the portions of the report with which I agree and disagree as follows:

A. Review of Top Ten Most Dangerous Pesticides

I am in full agreement that many of the old pesticides which were registered 20 and 30 years ago pose a potential health risk today. However, requiring the EPA to speed up its reregistration of previously approved pesticides beyond what they are already doing under what many consider to be an ambitious schedule may be unrealistic. In addition, many of the uses of pesticides mentioned have been cancelled while others are currently under special review.

B. The Scientific Advisory Panel

The role of the Scientific Advisory Panel (SAP) in peer review of EPA decisions is essential to good decision making. I agree that a broad range of expertise among the panels members is needed. The EPA should be more sensitive to conflicts of interest.

C. Suspension and Imminent Hazard

I agree that the current process needs to be streamlined and the EPA should have more flexibility to suspend pesticides in order to maintain public safety and its own credibility. It may well be necessary to reexamine the current definition of imminent hazard, with the objective of making it a more realistic and useful tool for suspension actions.

D. Overall Plan and Schedule

The Subcommittee report concludes that there is no plan in place to reregister active ingredients in chemicals currently in use. However, the FIFRA Amendments of 1988 provide for the reregistration of all active ingredients within nine years and for additional resources for the EPA to accomplish this task. The EPA has published a general schedule as required by the FIFRA Amendments, and to date has met all of the statutory deadlines established by those amendments.

E. Resolve Conflicts Between Risk-Benefit Analysis and Delaney Clause

The EPA has recognized the need to modify Delaney and in October 1988 published in the Federal Register a proposal to deal with this problem which could prevent the entry into the market of newer lower risk pesticides. The EPA needs a rational negligible risk standard and this is an issue that I anticipate will be addressed in the Administration's food safety proposals.

F. Neurotoxicity Testing

I agree that the EPA must improve its procedures for premarket testing of chemicals for neurotoxicity. While the EPA has developed draft guidelines which they expect to put in place in the future, this is an area which warrants accelerated action.

G. Shorter Review Time for Certain Chemicals

I agree that the cancellation process should be streamlined and shortened. Again, I anticipate that this will be addressed in the Administration's food safety proposals.

H. Tolerance Levels Should Equal Safe Exposure Levels

I agree that tolerance levels for older pesticides need to be reassessed but it is important not to set them so low that food is unnecessarily seized or declared adulterated. It is important to recognize that from the "farm gate to the dinner plate" residue levels can fluctuate significantly, particularly on

contact pesticides versus systemic pesticides. It is equally important, within the parameters of safety, not to reduce the tolerance level for a pesticide to a level where it would no longer protect the food product from disease or pests.

I. Setting Tolerances Based on Health Effects and Effects on Subpopulations

I agree that the EPA needs better data on food consumption and subpopulations, particularly for young children. My primary reason for introducing legislation, S.1061, to ban the use of Alar on food products stemmed from my deep concern for the health and safety of children.

J. Cumulative and Synergistic Effects

I am not certain that the reports recommendation for more aggressive testing on the synergistic effects of combining pesticides on commodities is realistic given the EPA's resources and the multitude of variables involved in such testing. For instance, the effects of combining chemical A with chemical B may have a different effect on individuals based on their diet, or whether they drink alcohol or smoke. The actual regulatory value of such an investigation may be questionable.

K. Inert Ingredients

I agree that the EPA should examine the use of dangerous inert ingredients in pesticides. While I understand that the EPA has a plan and is looking at a list of inerts of concern, I encourage them to move forward expeditiously.

L. Detection of Residues in Food

I agree that a better job can be done in this area. It is important to have active cooperation between the USDA and EPA in this area.

I am anxious for the Congress to confront directly these and other issues concerning a safe food supply. The time has come for Congress to meet the challenge of revising FIFRA and to develop with the Administration an effective food safety program. While some may differ in their approach to achieving this important goal, I am confident that all will participate in good faith and we will be successful.

The Alar controversy was in many respects unique. It is my hope that such a situation shall never recur. It is unfortunate that a problem of such magnitude and impact had to occur before the defects in the FIFRA statute could be identified.

APPENDIX 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 29 1989

THE INSPECTOR GENERAL

Honorable Joseph I. Lieberman
United States Senate
Washington, DC 20510

Dear Senator Lieberman:

This is in response to your letter of May 15, 1989, also addressed to the Administrator, which raised several issues concerning the Environmental Protection Agency's (EPA) review of the pesticide daminozide (Alar). You had requested that EPA and the Inspector General conduct simultaneous investigations into the assessment of crop exposure to daminozide. Specifically, you asked us to determine how EPA developed its estimate that only five percent of the apple crop had been exposed to daminozide, and whether EPA will do an independent study to determine how much of the apple crop is treated with Alar.

We found that EPA has been inconsistent in their estimates of Alar use. We did not review every report made by EPA, but the following samples should demonstrate this inconsistency.

-- On March 16, 1989, EPA testified before the Subcommittee on Children, Family, Drugs and Alcoholism, Committee on Labor and Human Resources, U.S. Senate that Alar was used by 5 percent of the Nation's apple growers, down from 25 percent prior to 1985.

-- On May 8, 1989, EPA reported to Governor Richard F. Celeste, State of Ohio that Alar was used by 5 percent of the Nation's apple growers, down from 40 percent in 1985.

-- On May 10, 1989, EPA reported to the Honorable Christopher H. Smith, House of Representatives, Alar was used by 5 percent of the Nation's apple growers, down from 25 percent in 1985.

-- On May 15, 1989, EPA testified before the Subcommittee on Toxic Substances, Environmental Oversight, Research and Development, Committee on Environment and Public Works, U.S. Senate that Alar was used by approximately 5-15 percent of the Nation's apple growers, down from 24 percent in 1985.

-- On June 23, 1989, EPA reported to the Honorable Elliot L. Engel, House of Representatives, Alar was used by approximately 5-15 percent of the Nation's apple growers, down from 25 percent in 1985.

Although these variations do not significantly impact on regulatory decisions regarding Alar, they did contribute to the substantial confusion over how much of the apple crop was treated with Alar.

Alar usage estimates provided in the earlier comments were based on data supplied by two marketing research companies. Using this data, staff within the Economic Analysis Branch of the Office of Pesticide Programs reported, in a December 1987 memorandum, Alar usage by crop and Region for 1984-85, The Branch estimated the percent of crop treated for the 1984-85 period to be 29 percent. This estimate was later revised down to 24 percent for the regulatory action to ban Alar. In 1986, one of the marketing research companies estimated three percent and the other estimated five percent of the crop was treated with Alar. One of the companies also collected data for 1987 and estimated that 11 percent of the apple crop was treated. Thus, a range for the 1986-87 period would be 3-11 percent.

A draft Special Review document was circulated by the Office of Pesticides Program in March of 1989 and finalized in May of 1989 based on data provided by the manufacturer in December 1988. These data provided state by state figures on sales of Alar and estimates of the amount used on apples. Assuming the farmer used all the Alar purchased, the data indicate that about 5 percent of the crop was treated in 1986, about 11 percent in 1987 and about 8 percent in 1988. In this document, EPA revised its estimate of current crop usage from 5 percent to a range of 5-15 percent.

We could not obtain an adequate explanation for several anomalies in EPA's reporting. First, EPA officials could not explain why the pre-1985 percentages reported to the public varied from report to report despite the fact that it had been calculated and reported in an internal memo by the Economics Analysis Branch. Second, EPA reported usage of Alar was not consistent with the supporting data. EPA repeatedly reported Alar usage in terms of a percent of apple growers. However, the

data provided as support clearly indicate that it should have been reported in terms of a percent of the crop treated. EPA officials agreed that the percent of crop treated provides a substantially more accurate estimate, but they could not explain how or why the change occurred. They stated that all future reporting will be in terms of a percent of crop treated. Third, EPA's earlier estimate that 5 percent of the crop was treated with Alar appears low based on the supporting data that showed a range from 3 to 11 percent for 1986 and 1987. EPA officials stated that these earlier estimates were rounded to facilitate easier and simpler reporting. The later estimate of 5 to 15 percent was based on the sales data from the manufacturer.

In our opinion, EPA did not diligently review all of the available data before preparing its public statements. Considering all of the available data, which indicated an increasing trend from 1986, reporting a range of 5 to 15 percent would have been more prudent than the earlier estimates of 5 percent. Also, the rounding of the estimate at only 5 percent had no basis. Clearly, additional care should have been taken to ensure that accurate information was consistently reported in all Agency pronouncements.

EPA officials stated they have no plans to perform an independent survey to determine how much of the apple crop is treated with Alar. They based this position on their proposed regulations to remove Alar from the market, and Uniroyal's subsequent announcement that they would voluntarily remove it until the regulatory process is completed.

We had hoped to include an analysis of the completeness and accuracy of the Agency's answers to these same questions. However, to date EPA has not issued its response. In order not to delay further your need for this information, we are providing our response at this time. If after reviewing EPA's letter, you find that you need clarification or additional data, we will, of course, continue to assist you. Should your staff have any questions about this matter, please have them contact Ernest E. Bradley III, Assistant Inspector General for Audit, at 382-4106.

You also asked that we investigate possible conflicts of interest involving members of EPA's Scientific Advisory Panel. Our investigation is complete; however, we are awaiting a determination from the Office of Public Integrity, Department of Justice concerning their analysis of certain aspects of our investigation. Upon receipt of this determination we will provide you with further details.

Sincerely,

John C. Martin

John C. Martin

APPENDIX 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 12 1989

THE ADMINISTRATOR

Honorable Harry Reid
Chairman, Subcommittee on Toxic Substances,
Oversight, Research and Development
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letters of May 15, 1989, and July 24, 1989. Additional requests for information were also made at the hearing held by the Subcommittee on Toxic Substances, Oversight, Research and Development on May 15, 1989. You have raised several issues involving the Environmental Protection Agency's (EPA's) review of the pesticide daminozide (Alar). The Office of the Inspector General has provided an independent audit of the usage figures the Agency developed for Alar. The Inspector General will also be investigating and responding to the allegations that members of the Scientific Advisory Panel (Panel) engaged in conduct that may have involved conflict of interest.

I would like to provide you with an explanation of the policies and procedures related to the Alar usage figures, and several other questions regarding the Panel. I apologize for the delay in answering your May 15 letter, although I understand that some of your questions were answered as part of the confirmation process for Linda Fisher as Assistant Administrator for Pesticides and Toxic Substances.

First, you express concern about the difference between the estimates of the percent of the apple crop treated with Alar made by the Agency in January, when the apple tolerance extension was announced, and estimates from Consumers Union (CU), the staff of the National Academy of Sciences (NAS), and others.

ALAR EXPOSURE AND RISK ASSESSMENT

Before explaining just how the different estimates were derived, I think it is important to emphasize that EPA has never used the percent of apple crop treated in estimating dietary risks for Alar. For risk assessment purposes, the apple residue values used to estimate dietary exposure for Alar were based on a 1986

direct marketbasket sampling, conducted by Uniroyal, of raw apples, adult apple sauce and juice, and baby apple sauce and juice. We believe that marketbasket monitoring data, when available, are the best data to use for estimating consumer exposure, since it reflects residues in commodities at the point of sale to consumers.

The Alar marketbasket survey samples were taken at a time when EPA estimated that 24 percent of the apple crop was treated. Alar usage has declined since the 1986 marketbasket survey, and consequently people are experiencing less exposure and risk during the anticipated phase-out of the chemical. (As you know, the manufacturer has agreed to halt sale of food-use Alar products pending a final cancellation decision by EPA.)

Since marketbasket surveys are seldom available, EPA often estimates dietary risks on the basis of field trial data; absent field trials, the Agency uses the assumption that residues are present at tolerance level (the maximum allowable residue level). Under either of these circumstances, estimates of the percentage of a crop treated plays a significant role in projecting dietary exposure to a pesticide. If no reasonable estimate of the percentage of crop treated is available, EPA has to assume 100% is treated, which is a worst-case approach almost never reflective of real-world conditions.

ALAR USAGE SURVEYS

In the Alar case, data on the percent of crop treated was developed and presented to the public because it is important information for the assessment of Alar's benefits, contained in the Notice of Preliminary Determination issued on May 12, 1989. These data are used in assessing the impact of the pesticide on crop production.

As you know, we revised our January estimate of the percent of crop treated, 5 percent, up to 5-15 percent in April. In January, EPA had made only a preliminary estimate of the percent of the apple crop treated. Apples are a widely grown and heavily produced commodity, with some 8 billion pounds harvested annually. It is difficult to obtain a precise estimate of the percent of crop treated.

In January, two proprietary pesticide usage market surveys were used: one by Doane Marketing Research, Inc., and another by Technomics Consultants. These two surveys showed that 1986 usage dropped to 3 to 5 percent of crop treated (from 24 percent in 1985) following the flurry of regulatory and public concern in 1985. Technomics data were available only for 1986 and Doane's data for 1986 and 1987. The 1987 Doane's data showed increased use in 1987 and served as the basis for an estimate that between 4 and 8 percent of the apple crop were treated in 1988 with Alar. This range was simplified to 5 percent to facilitate communication with

the press and public. In developing our most recent estimate, the Agency had access to updated Doane's data plus Uniroyal sales data for individual states. These two sets of data indicate that 1986 - 1988 usage was in the 5-15 percent range.

In sum, it is estimated that approximately 24 percent of the apple acreage was treated in 1985 and in 1986 usage fell substantially. Based on proprietary surveys and Uniroyal sales data, usage in the years since 1985 has been in the 5-15 percent range. The Agency is not planning to do an independent survey of its own because we are convinced that use today is less than it was in 1985. The 1985 usage is reflected in the 1986 marketbasket survey which provided the exposure information used in our risk assessment.

Turning to your next question, our current estimates of percent of crop treated (5-15 percent) are consistent with CU and independent surveys by CBS News and others. Our estimates are for the entire apple crop -- all varieties of apples, over the course of a full year, for the entire country, intended for both the fresh market and processing. CU and CBS looked at fresh apples at the time of year when apples containing Alar residues are most likely to be found. Allow me to explain the reasons for these differences.

Apples are produced primarily for the fresh market, but some are grown specifically for processing and others are diverted from the fresh market to the processing market. Because one of the major benefits of daminozide is a longer storage life for certain apple varieties, growers will treat those apples which are expected to be retained in storage for sale late in the season. Therefore, a sample of apples taken in the spring or summer would probably contain a higher percentage of apples testing positive for daminozide than a comparable sample taken in the fall harvest season.

CU, CBS and other independent sampling should be compared with the 1986 marketbasket survey data rather than the Agency's more recent estimated percent of crop treated values. In the 1986 survey, about 64 percent of the fresh apples sampled between February and June contained daminozide residues at or above 0.3 ppm. The CBS survey, conducted in April, found 30 percent at or above 0.3 ppm. A survey conducted by the Los Angeles Times in March of this year found 26 percent at or above 0.5 ppm, compared to the 1986 survey which found 56 percent of the samples taken between February and June contained residues at or above 0.5 ppm. The Consumer Union data show a smaller decrease (55 percent at or above 0.4 ppm). However, this was a very limited sample, consisting only of red apples in the New York City area. These comparisons support EPA's conclusion that the percent of the apple crop treated has decreased. In effect, all data sources available to EPA -- including confidential production data, sales data provided by

Uniroyal, surveys conducted by two agricultural research firms, and recent monitoring data -- show a decline in usage and percent of crop treated since 1985.

In summary, the percent of crop treated figure played no role in estimating cancer risk since more reliable residue values from direct sampling of raw and processed apples in the market place were available to estimate exposure. Second, estimating the percent of crop treated, particularly in the emotionally charged environment that surrounds daminozide, is difficult at best. When the Agency used the 5 percent estimate, it was really summarizing a range which at that time was thought to be 4 to 8 percent and which later was revised upward to 5 to 15 percent. Third, national percent crop treated values cannot be compared meaningfully to limited sampling efforts where, depending on several variables, particularly the time of year and variety sampled, the number of positive apple samples will differ greatly from the national percent of crop treated. Unfortunately, EPA did not effectively communicate these facts to the public at that time.

CONFLICTS OF INTEREST FOR SCIENTIFIC ADVISORY PANEL

With regard to your question regarding the steps taken to review the backgrounds of potential Scientific Advisory Panel appointments, both general conflict of interest regulations and specific FIFRA provisions make specific requirements. Panel members are subject to the provisions of Title 40, Code of Federal Regulations, Part 3, Subpart F --Standards of Conduct for Special Government Employees. Included in Subpart F is a provision that each nominee selected by the Administrator must submit, at the time of appointment, a Confidential Statement of Employment and Financial Interests. In addition, the SAP Charter provides that an officer and/or employee of an organization producing, selling, or distributing pesticides and any other person having a substantial financial interest (as determined by the Administrator) in such an organization, as well as an officer or employee of an organization representing pesticide users shall be excluded from consideration as a nominee for membership on the Panel.

In carrying out section 25(d) of FIFRA, the Administrator requires all nominees to the Panel to furnish information concerning their professional qualifications, including information on their educational background, employment history, and scientific publications. Section 25(d) requires the Administrator to publish the name, address, and professional affiliations of each nominee in the Federal Register.

You are also concerned about the types of outside consulting activities in which Panel members may engage. We look for highly qualified scientists to serve on this Panel. Because they are well respected, their expertise is in high demand by many sources, including industry. It is, therefore, difficult to find highly

qualified individuals who do not also consult with industry. I am, nevertheless, very sensitive to the need for maintaining an objective Panel. For this reason, I fully support our current conflict of interest requirements which provide that Panel members recuse themselves from decisions involving any companies for which they are currently consulting. In summary, Panel members are subject to the conflict of interest rules that apply to Special Government Employees or consultants. These rules are contained in EPA Ethics Advisory 88-6 (July 5, 1988). I am enclosing a copy of this advisory for your information.

I want to emphasize that I am strongly committed to ensuring the integrity and viability of the Science Advisory Panels used by the Agency. I expect that the EPA Ethics Advisory will be rigorously implemented and wish to prevent any conflict of interest from improperly affecting Agency decision making.

I firmly believe that it is possible to maintain a Panel with high scientific standards which is also held to high ethical standards. It is important that the American public have confidence in both the technical competence and objectivity of the scientists who make the important scientific decisions about the hazards of pesticides. However, a complete prohibition of all outside consulting with the chemical industry may adversely affect the quality of panelists who would be willing to serve. I will be working with our General Counsel to review our existing advisory committee procedures on conflicts of interest to ensure that they are strong, and will make any improvements that are necessary.

With regard to post-employment conflicts of interest, the only post-employment restriction for Panel members is a rather narrow proscription against certain types of representational activity. Panel members are considered the same as federal employees for purposes of conflict of interest. The former Government employee is prohibited from acting as "agent or attorney" regarding a "particular matter involving a specific party or parties" in which he or she ever participated as a Government employee. The definition of "specific party" is critical for determining when restrictions apply. For example, a proceeding to suspend or cancel a pesticide for a particular use involves a registrant as a "specific party" and, therefore, a Panel member would be restricted from post-employment communication with the Government regarding the suspension or cancellation with the intent to influence if he or she had acted as a Government employee in the suspension or cancellation action. However, many policy decisions, such as how to estimate dietary exposure, generally do not involve registrants as "specific parties." In such cases, there is no post-employment restriction. In addition, there is no restriction against serving as a "consultant" for industry on such issues after the expiration of one's term of membership on the Panel.

MEMBERSHIP OF THE SCIENTIFIC ADVISORY PANEL

You also asked whether EPA has any plans to add experts with public health or pediatrics backgrounds to the Panel. Let me explain what types of expertise EPA seeks in the nominees to the Panel. In determining the specific scientific discipline(s) which are needed to advise the Agency, we consider the types of issues which the Panel has addressed, as well as the issues expected to arise in the future. Often, the scientific issues presented to the Panel have dealt with the carcinogenicity of selected pesticides which the Agency has reviewed in its internal Peer Review process or for which Special Review has been initiated. Such issues benefit from comments by experts in several fields, including a toxicologist knowledgeable in the evaluation of animal laboratory studies of carcinogens and the variables to be considered in extrapolating these data to human risk, a veterinary pathologist capable of evaluating the significance of pathological changes in several species for relevance to humans, and a biostatistician to review the statistical evidence in relation to human risk assessment. Such expertise is generally useful for the evaluation of other scientific issues presented to the Panel, for example, the recent Agency proposal to refine the dietary exposure analysis of the Tolerance Assessment System for acutely toxic pesticides such as aldicarb. Thus, we recently requested nominees with expertise in toxicology, veterinary pathology, and biostatistics.

Although the standing membership of the Panel is limited by law to seven members who serve staggered appointments, the Agency routinely brings in, on an ad hoc basis, scientists with specific expertise to assist the Panel members on issues requiring such expertise. For example, in considering the issue of acute dietary exposure to aldicarb mentioned above, an expert in cholinesterase inhibition served as a temporary member of the Panel. When the Agency considered revising neurotoxicity data requirements for pesticides, a specialized subpanel of experts was formed to consider the issues raised by the proposal. Thus, we make every effort to have a balance of expertise on the standing Panel and to supplement this expertise, as necessary. The principal requirement for membership is the possession of the technical qualifications to assess the effects of pesticides on health and the environment, rather than affiliation with a particular advocacy position.

In the August 3 letter from Linda Fisher to Senator Lieberman, she stated that she will place a new emphasis on the search for pediatricians and public health experts to be included in the deliberations of the Panel on relevant issues, and also to be considered for membership. I urge Congress to consider expanding the Panel as part of its deliberations over amending FIFRA. An expanded Panel size will assist in accommodating these two areas of emphasis. In the meantime, as positions on the Panel open up,

Ms. Fisher and I will be seeking pediatricians and public health officials who have the necessary credentials.

EPA STAFF TOXICOLOGISTS

You are also concerned about whether we have a sufficient number of toxicologists to handle the increased workload resulting from FIFRA 88 amendments. Currently, we have 56 individuals who spend the majority of their time engaged in toxicological analysis of chemicals for registration and reregistration. We use a wide variety of scientists who function as toxicologists, including microbiologists, pharmacologists, chemists and geneticists to evaluate test data. Because of difficulties in hiring trained toxicologists, we frequently hire from other disciplines and then train them in toxicology, or hire toxicologists who are new graduates.

We are currently running a very aggressive recruiting campaign for qualified personnel to support our efforts to implement the accelerated reregistration process called for in the 1988 FIFRA amendments. We have established outreach programs all over the country, and I think we are being particularly effective in reaching targets of opportunity which had been previously unexploited. However, we are in many instances searching for personnel who are in demand because of their highly technical skills and we do experience some difficulty in both recruiting and retaining them. At this time it is difficult to project the exact number of positions we will need because we do not know the number of chemicals that will be reregistered. We should be able to provide an estimate by early 1990.

INTERPRETATION OF "IMMINENT HAZARD"

A final question relates to EPA's interpretation of the term "imminent hazard" as it relates to the suspension of a pesticide. As you pointed out in your July 24 letter, FIFRA provides a more restrictive interpretation than other EPA statutes. I am enclosing a legal analysis by our Office of General Counsel which discusses this issue.

Thank you for this opportunity to address the issues raised concerning EPA's review of Alar. I hope this information is helpful. Please let me know if you need additional information.

Sincerely yours,

William K. Reilly

Enclosures

APPENDIX 3

TABLE 3-9 Estimated Oncogenic Risk from Dietary Exposure to 25 Pesticides

Active Ingredient	Food Crop Uses (number)	Type of Pesticide	Risk	Weight-of-the Evidence Classification	Year of First Tolerance
Zineb	83	Fungicide	7.17×10^{-4}	B_2[a]	1955
Captan	83	Fungicide	4.74×10^{-4}	B_2	1955
Maneb	56	Fungicide	4.42×10^{-4}	B_2[a]	1957
Permethrin (Ambush, Pounce)	43	Insecticide	4.21×10^{-4}	C	1978
Mancozeb (Dithane M-45)	44	Fungicide	3.38×10^{-4}	B_2[a]	1962
Folpet	41	Fungicide	3.24×10^{-4}	B_2	1955
Chlorothalonil (Bravo)	47	Fungicide	2.37×10^{-4}	NA	1961
Metiram	11	Fungicide	1.15×10^{-4}	B_2[a]	1967
Benomyl	101	Fungicide	1.13×10^{-4}	C	1972
O-Phenylphenol	22	Fungicide	9.99×10^{-5}	NA	1955
Acephate (Orthene)	34	Insecticide	3.73×10^{-5}	NA	1972
Alachlor (Lasso)	25	Herbicide	2.42×10^{-5}[c]	B_2	1969
Parathion	98	Insecticide	1.47×10^{-5}	C	1955
Oxadiazon (Ronstar)	26	Herbicide	1.21×10^{-5}	B_2	1977
Oryzalin (Surflan)	57	Herbicide	1.14×10^{-5}	C	1974
Pronamide (Kerb)	25	Herbicide	7.77×10^{-6}	C	1972
Cypermethrin (Ainmo, Cymbush)	7	Insecticide	3.73×10^{-6}	C	1984
Ethalfluralin (Sonalan)	18	Herbicide	3.56×10^{-6}	NA	1982
Diclofop methyl (Holelon)	5	Herbicide	2.04×10^{-6}	NA	1980
Metolachlor (Dual)	40	Herbicide	1.44×10^{-6}	C (pending)	1976
Cyromazine (Larvadex)	4	Insecticide	3.58×10^{-7}	NA	1984
Terbutryn	4	Herbicide	2.86×10^{-7}	C	1959
Glyphosate (Roundup)	134	Herbicide	2.73×10^{-7}	C	1976
Fosetyl Al (Aliette)	1	Fungicide	3.29×10^{-8}	C	1983
Azinphos-methyl (Guthion)	78	Insecticide	1.68×10^{-9}	D	1956

NOTE: In this table and in those following, risk estimates are based on EPA data and methods using the TAS U.S. mean consumption estimates. They assume that residues are at the tolerance level, that 100 percent of all acres are treated, and that exposure occurs over a 70-year lifetime.

B_2 indicates a probable human carcinogen. C indicates a possible human carcinogen. D indicates not classifiable as to human carcinogenicity. NA indicates that the pesticide has not been classified by EPA.

[a]The classification is for the EBDC metabolite ethylene thiourea.

[b]The risk estimate assumes residues at the level of detection, or 0.05 ppm, for all meat, poultry, and dairy products with tolerances for chlordimeform.

[c]This risk estimate does not include the use of alachlor on potatoes because this use was withdrawn by the registrant when these risk estimates were calculated.

Regulating Pesticides in Food: The Delaney Paradox, © 1987 by the National Academy of Sciences.